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Briefing on How To Use the Federal Register
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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

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2. The relationship between the Federal Register and Code of Federal Regulations.
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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

(TWO BRIEFINGS)

WHEN: September 13 at 9:00 am and 1:30 pm
WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

DENVER, CO

WHEN: September 21, 9:00 am–12 noon
WHERE: Colorado National Bank Building 12345 W. Alameda Parkway, Room 207, Lakewood, CO
RESERVATIONS: Federal Information Center 1–800–359–3997

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Electronic Bulletin Board
Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 303

RIN 3064–AB36

Applications and Publication Requirements; Establishment and Relocation of Remote Service Facilities

AGENCY: Federal Deposit Insurance Corporation (FDIC or Corporation).

ACTION: Final rule.

SUMMARY: The Board of Directors (Board) of the FDIC is revising its application and publication requirements for the establishment and relocation of remote service facilities (RSFs). The intended effect of this rule is to lessen the regulatory burden on state nonmember banks and state-licensed branches of foreign banks.

EFFECTIVE DATE: This rule is effective August 23, 1994.

FOR FURTHER INFORMATION CONTACT: Curtis L. Vaughn, Examination Specialist, Division of Supervision (202/898–6759), Federal Deposit Insurance Corporation, 1776 F Street, NW., Washington, DC 20429; or Jeffrey M. Kopchik, Counsel, Legal Division, (202/898–3872), Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

No additional collections of information pursuant to § 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) are contained in the final rule. Consequently, no information was submitted to the Office of Management and Budget for review.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the FDIC hereby certifies that the final rule will not have a significant impact on a substantial number of small entities.

The FDIC has reached this conclusion because the effect of the rule will be to reduce the recordkeeping, reporting and compliance requirements that are imposed upon small entities rather than to increase them. This is because the final rule seeks to create a blanket approval process for requests that must receive the prior written consent of the FDIC. The final rule imposes no new recordkeeping or reporting requirements upon small entities since notices required are abbreviated versions of letter applications currently required of banks. Furthermore, most institutions would not be required to give public notice of the transaction which would reduce burden on the requesting institutions.

Effective Date

The necessity for a 30-day delay in effective date has been waived since this rule relieves a restriction. 5 U.S.C. 553(d)(1).

Discussion

On April 26, 1994 the FDIC published for public comment a proposed revision to part 303 of its regulations concerning the application and publication requirements for the establishment and relocation of remote service facilities. 59 FR 21676 (April 26, 1994). In general, the proposal sought to reduce the regulatory burden on state nonmember banks and state-licensed branches of foreign banks by lessening the application and notice requirements which an institution must satisfy before it may establish or relocate an RSF. Even more streamlined procedures were set forth for banks with Community Reinvestment Act (CRA) ratings of satisfactory or better.

The FDIC received a total of eight comment letters in response to its proposal. Five of the letters were from banks or their holding companies and three were from industry trade associations. All of the letters enthusiastically supported the proposed revisions.

The FDIC Board specifically requested comment on whether the proposed revision should treat different types of RSFs differently, *i.e.*, an RSF which caters exclusively to one bank's customers as opposed to a shared RSF which is utilized by customers of many banks. The four of eight commenters which addressed this question all urged the FDIC to adopt the same standards for all types of RSFs, which is the approach that was taken in the proposal and has been retained in the final rule.

Under the prior regulation, banks desiring to establish an initial RSF were required to comply with all the application and publication requirements applicable to the establishment of a "brick and mortar" branch office. Successive RSFs could be established or relocated without a formal application pursuant to somewhat less involved requirements. The prior regulation did not differentiate based upon the condition of the institution submitting the application; the only difference it recognized was whether or not this was an initial application.

In view of the limited investment represented by an RSF, the fact that all the information in the FDIC's possession indicates that consumers are of the opinion that RSFs are a convenient and desirable banking service and the support expressed by all the commenters, the FDIC is amending its regulation concerning the establishment and relocation of RSFs to lessen the application and notice requirements which an institution must satisfy before it may establish or relocate an RSF. Furthermore, the final regulation sets forth even more streamlined procedures for banks with CRA ratings of satisfactory or better.

Specifically, § 303.2(c) provides that a state nonmember bank or an insured state-licensed branch of a foreign bank whose most recent CRA rating is Satisfactory or better may establish and operate or relocate an RSF by filing a letter with the appropriate FDIC regional director. The letter shall contain the location of the RSF and either a representation that the site is not included in or eligible for inclusion in the National Register of Historic Places or written verification that in the opinion of the appropriate state historic preservation officer the establishment or relocation of the RSF will have no adverse effect on a historic site. Unless the institution is notified otherwise by the FDIC within seven days of receipt of the letter, the institution may establish or relocate the RSF. The public notice requirements are being dispensed with in this case. See § 303.2(c)(2). However,

if the institution cannot make such representations concerning compliance with the National Historic Preservation Act, 16 U.S.C. 470 *et seq.*, it shall proceed pursuant to § 303.2(c)(3).

In the event that the state nonmember bank or insured state-licensed branch's most recent CRA rating is not Satisfactory or better, § 303.2(c)(3) provides that the institution shall file the letter described in § 303.2(c)(2) and comply with the existing notice provisions of § 303.6(f). Unless the institution is notified otherwise within fifteen days after completion of processing of the letter, the institution may establish or relocate the RSF. In the event that a protest is filed or other objection is taken, the institution may not proceed until the FDIC provides written notice of its approval.

The remaining revisions are to § 303.6(a) and (f) of the FDIC's regulations. They are technical in nature in order to conform these sections, which concern application procedures and public notices of application filings, to the new procedures set forth in § 303.2. First, § 303.6(a)(2) and (3) have been revised to take into account the different procedures set forth in § 303.2(c) for institutions with CRA ratings of Satisfactory or better as opposed to institutions with CRA ratings of less than Satisfactory. Second, the heading of § 303.6(f)(1)(A) has been revised to make it clear that section applies to applications to establish an RSF. Third, § 303.6(f)(2) has been amended to delete any reference to remote service facilities. This is being done in order to conform this section of the regulation with the revision to § 303.6(a) which deletes the publication requirement for applicants with CRA ratings of satisfactory or better.

The Board is of the opinion that this is a sensible revision which will substantially reduce the regulatory burden imposed on state nonmember banks and insured state-licensed branches of foreign banks that desire to establish or relocate an RSF without adversely affecting the FDIC's ability to assure the safety and soundness of the insured financial institutions it regulates or its responsibilities under the CRA. Thus, the proposal is being adopted in final form without change.

List of Subjects in 12 CFR Part 303

Administrative practice and procedure, Authority delegations (Government agencies), Bank deposit insurance, Banks, banking, Reporting and recordkeeping requirements, Savings associations.

For the reasons set forth in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation hereby amends part 303 of title 12 of the Code of Federal Regulations as follows:

PART 303—APPLICATIONS, REQUESTS, SUBMITTALS, DELEGATIONS OF AUTHORITY, AND NOTICES REQUIRED TO BE FILED BY STATUTE OR REGULATION

1. The authority citation for Part 303 continues to read as follows:

Authority: 12 U.S.C. 378, 1813, 1815, 1816, 1817(a)(2)(b), 1817(j), 1818, 1819 ("Seventh" and "Tenth"), 1828, 1831(e), 1831(o), 1831p-1(a); 15 U.S.C. 1607.

2. In § 303.2, paragraph (a), introductory text is amended by removing the second parenthetical in the first sentence, the parentheticals in the second and third sentences, and by removing ", relocate a remote service facility" and "other than a remote service facility" from the fourth sentence, and paragraph (c) is revised to read as follows:

§ 303.2 Applications by insured state nonmember bank to establish a branch, move its main office or relocate a branch.

* * * * *

(c) *Special procedures for remote service facilities.* (1) For purposes of this section, *establishing* means owning or leasing a remote service facility either individually or jointly.

(2) An insured state nonmember bank or an insured state-licensed branch of a foreign bank whose most recent Community Reinvestment Act rating is Satisfactory or better and who desires to establish and operate or relocate a remote service facility (RSF) shall file a letter with the appropriate regional director. The letter shall contain the exact location of the proposed or relocated RSF, including street address (unless one has not been assigned to the location), and either a representation that the site of the proposed or relocated RSF is not included in or eligible for inclusion in the National Register of Historic Places or written verification that in the opinion of the appropriate state historic preservation officer the establishment or relocation of the RSF will have no adverse effect on a historic site. Unless the institution is notified otherwise by the FDIC within seven days of receipt of the letter, the institution may establish and operate or relocate the RSF. In the event that the institution cannot represent in good faith that the site of the proposed or relocated RSF is not included in or eligible for inclusion in the National Register of Historic Places or evidence that written verification has been obtained from the appropriate state historic preservation officer, the institution shall proceed pursuant to paragraph (c)(3) of this section.

(3) An insured state nonmember bank or an insured state-licensed branch of a foreign bank whose most recent Community Reinvestment Act rating is not Satisfactory or better and who desires to establish and operate or relocate an RSF shall file the letter described in paragraph (c)(2) of this section and comply with the notice provisions of § 303.6(f). Unless the institution is notified otherwise by the FDIC within 15 days after completion of processing of the letter, the institution may establish and operate or relocate the RSF; provided however, that in the event that a protest is filed with the FDIC or other objection is taken prior to completion of processing the letter, the institution shall not establish and operate or relocate the RSF until the FDIC provides written notice of its approval.

3. Section 303.6 is amended by removing and reserving footnote 5 and by revising paragraphs (a)(2), (a)(3), the heading of paragraph (f)(1)(ii)(A), and paragraph (f)(2) to read as follows:

§ 303.6 Application procedures.

(a) * * *

(2) Applications by insured state nonmember banks to establish branches, including applications to establish remote service facilities by banks whose most recent Community Reinvestment Act rating is not Satisfactory or better or who cannot represent compliance with the National Historic Preservation Act;

(3) Applications by insured state nonmember banks to move their main office or relocate their branch offices, including applications to relocate remote service facilities by banks whose most recent Community Reinvestment Act rating is not Satisfactory or better or who cannot represent compliance with the National Historic Preservation Act;

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(A) *Applications to establish a branch, including a remote service facility.* * * *

* * * * *

(2) *Notice by posting.* In the case of applications to move a main office or relocate a branch, in addition to the notice by publication described in paragraph (f)(1) of this section, notice of the publication shall be posted in the public lobby of the office(s) to be moved or relocated, if such public lobby exists, for at least 21 days beginning with the date of the last published notice

required by paragraph (f)(1) of this section for applications to move a main office; and for at least 15 days beginning with the date of the publication notice required by paragraph (f)(1) of this section for applications to relocate a branch.

* * * * *

By order of the Board of Directors.

Dated at Washington, D.C., this 9th day of August, 1994.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Acting Executive Secretary.

[FR Doc. 94–20535 Filed 8–22–94; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 101, 111, 123, 128, 141, 143, 145, 148, 159

[T.D. 94–71]

RIN 1515–AB53

Express Consignments; Formal and Informal Entries of Merchandise; Administrative Exemptions

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Interim regulations; Notice of Effective Date.

SUMMARY: This document gives notice that the interim regulations regarding express consignments, formal and informal entries of merchandise and administrative exemptions which were published in the **Federal Register** on June 13, 1994, will become effective on August 23, 1994. A motion for a preliminary injunction which would have prevented Customs from implementing and making effective these interim regulations was denied by the United States Court of International Trade on August 16, 1994. The temporary restraining order which was issued on July 25, 1994, enjoining Customs from implementing and making effective the interim regulations on its scheduled effective date of July 28, 1994, pending the decision on the motion for the preliminary injunction, has expired.

DATES: The effective date of the interim regulations published at 59 FR 30289 is August 23, 1994.

FOR FURTHER INFORMATION CONTACT: William G. Rosoff, Office of Regulations and Rulings (202) 482–7040.

SUPPLEMENTARY INFORMATION:

On June 13, 1994, a document was published by U.S. Customs in the **Federal Register** (59 FR 30289) as T.D. 94–51 setting forth interim regulations implementing certain statutory amendments to the Customs laws contained in the Customs modernization provisions of the North American Free Trade Agreement Implementation Act and clarifying certain procedures for low-value shipments brought into the U.S.

The document provided for a 45-day delayed effective date, with a 30-day comment period preceding that effective date. The effective date was to become July 28, 1994, and comments were requested by July 13, 1994.

On July 25, 1994, the National Customs Brokers and Forwarders Association of America, Inc. filed a motion for a temporary restraining order with the United States Court Of International Trade (Court No: 94–07–00423). Pursuant to the motion, the temporary restraining order was issued by the court; consequently, Customs was restrained and enjoined from implementing and making effective the interim regulations. A document was published in the **Federal Register** (59 FR 38548) on July 28, 1994, informing the public that the effective date of the interim regulations was delayed.

A hearing on the motion for a preliminary injunction was held on August 9, 1994. On August 16, 1994, the Court of International Trade issued a decision (Slip. Op. 94–129) denying the motion and dismissing the case. Consequently, the temporary restraining order has expired and Customs is no longer restrained from making the interim regulations published as T.D. 94–51 effective. This document is notice that the interim regulations will become effective on August 23, 1994.

Customs will complete its ongoing analysis of all substantive comments received in response to the request for comments in the interim regulations before Customs issues final regulations on the subject matter.

Dated: August 18, 1994.

Samuel H. Banks,

Assistant Commissioner, Office of Commercial Operations.

[FR Doc. 94–20648 Filed 8–18–94; 12:45 pm]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Regulations No. 16]

RIN 0960–AD61

Supplemental Security Income for the Aged, Blind, and Disabled; Treatment of Promissory Notes in Home Replacement Situations

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: This regulation explains how the Social Security Administration treats promissory notes and similar installment sales contracts and the proceeds generated therefrom when received as a result of the sale of a home which is excluded from resources under the supplemental security income (SSI) program. This regulation provides for application of the "home replacement exclusion" in situations where timely reinvestment of the installments into another home, which is similarly excludable as the principal place of residence, is made.

EFFECTIVE DATE: This final regulation is effective August 23, 1994.

FOR FURTHER INFORMATION CONTACT: Regarding this **Federal Register** document—Henry D. Lerner, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1762; regarding eligibility or filing for benefits—our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION:

Section 1613(a)(1) of the Social Security Act (the Act) excludes an individual's home from resources for purposes of determining eligibility for SSI payments. Further, § 416.1212(d) of our regulations allows the proceeds from the sale of an excluded home to be excluded from resources to the extent the proceeds are intended to be used and are, in fact, used within 3 months of the date of their receipt to purchase a replacement home which is similarly excluded. When that regulation was published in 1975, conventional financial arrangements were the norm. It was reasonable to expect an individual to receive the full purchase price of the former home in cash and to reinvest fully and immediately all cash proceeds from the sale. Therefore, no provision was included in the regulations for the treatment of home purchase financing other than full cash payment at or near

the time of sale. Over the years, however, less conventional arrangements involving proceeds other than cash (such as promissory notes or installment sales contracts) have become more common.

Under our regulations defining resources in the SSI program at § 416.1201, promissory notes or installment sales contracts received as proceeds from the sale of a home are considered resources as long as the SSI claimant owns them and has the legal right to convert them to cash to be used for his or her support and maintenance. Such instruments can be excluded, however, under § 416.1212(d) if they are converted to cash and used for the purchase of a replacement home within 3 months of receipt of the note or contract. In fact, prior to September 1989, we required that they be so converted in order to be considered an excluded resource. Accordingly, under this interpretation, the claimant's options were limited to selling the house for cash (possibly below market value) or liquidating the promissory note or installment sales contract likely at a substantial loss. Either of these options could have jeopardized the opportunity to acquire or maintain a replacement home without losing SSI eligibility.

On September 11, 1986, the United States Court of Appeals for the Ninth Circuit rejected this interpretation of § 416.1212(d) in the case of *Hart* v. *Bowen*, 799 F.2d 567. The *Hart* case involved an individual who sold her home under an installment sales contract. She applied the downpayment she received toward the downpayment on a new home. She also applied each of the monthly installment payments she received toward the mortgage on the new home. Her SSI benefits were terminated because the installment contract from the sale of her former home constituted an excess resource. The Ninth Circuit Court of Appeals found that the current market value of an installment sales contract resulting from the sale of an individual's excluded home is part of the value of the replacement home and thus excluded from countable resources, provided the payments generated by the contract were reinvested timely in the excluded replacement home. In May 1987, as a result of the decision rendered by the Ninth Circuit in *Hart* v. *Bowen*, we issued Acquiescence Ruling AR 87–3(9) to comply with the decision in the Ninth Circuit States.

In September 1989, we changed our national practice and published Social Security Ruling SSR 89–5p, effective September 6, 1989. The ruling explained that the value of an installment sales contract constitutes a "proceed" from the sale of an excluded home which can be excluded from resources under § 416.1212(d) if: (a) the contract results from the sale of an individual's home as described in § 416.1212(a); (b) within 3 months of receipt (execution) of the contract, the individual purchases a replacement home which also fits the description in § 416.1212(a); and (c) all contract generated sale proceeds are reinvested in the replacement home within 3 months of receipt of such proceeds. In addition, the ruling provided that when payments against the principal that result from the installment sales contract are being reinvested timely (i.e., within 3 months of receipt) in a new home, such payments are also excluded from resources. The ruling further provided that if the home replacement exclusion is not applicable because one or more installment payments have not been timely reinvested, the exclusion may be applied effective with the month following the month of receipt of a timely reinvested payment.

This regulation codifies SSR 89–5p and reflects more completely our policy on the treatment of proceeds from the sale of an excluded home by designating the existing text in § 416.1212 paragraph (d) as paragraph (d)(1), and adding two new paragraphs (d)(2) and (d)(3), to explain the conditions under which the value of a promissory note or similar installment sales contract, and other proceeds from the sale, consisting of the downpayment and monthly installment payments towards the principal, will be excluded from being considered SSI resources. In addition, we are adding new paragraphs (e), (f), and (g) to § 416.1212 to explain the effects on SSI eligibility of failure to reinvest installment payments timely and the receipt of interest payments. When this final rule is published both SSR 89–5p and AR 87–3(9) will be rescinded.

Public Comments

We published the proposed rule with a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on October 13, 1993 (58 FR 52943). Interested persons and organizations were given 60 days to comment. The comment period closed on December 13, 1993. We received comments from only one commenter.

We considered carefully all of the comments which this individual made on the proposed rule. However, for the reasons stated below, we did not adopt any of them. Accordingly, the final rule is the same as the proposed rule. A summary of the comments and our responses are provided below.

Comment: The commenter disagreed with the policy to allow a person only 3 months to reinvest the proceeds from the sale of an excluded home into another home since the purchase of a home generally represents one of the largest transactions a person may make, one which would require time to make a wise decision. Thus, the commenter believes that it makes sense to give a person more time. The period should be increased from 3 months to 6 months similar to the time allowed for the disposal of other resources, such as retroactive title II or title XVI payments.

Response: We do not plan to change the 3-month time period for reinvestment. The substance of our regulatory revision focuses on how to evaluate as resources certain noncash proceeds from the sale of an excluded home and not on the time period of reinvestment. The time period has been longstanding program policy which was not questioned in the *Hart* decision. We would expect that individuals selling their homes would arrange for the purchase of a new home before the former home is sold. In addition, we have no evidence to support the commenter's contention that the current time period for reinvestment is too short.

Comment: The commenter criticized the proposed policy to count as a resource the value of the note as well as any proceeds not timely invested as being an "overly harsh penalty." Because the individual has immediate access only to the proceeds of the note that are "on hand" to meet his or her basic needs and not the value of the note itself, the commenter believed that only the proceeds should be considered a resource.

Response: This policy is consistent with the relevant provisions of the Act and other related regulations. Under section 1611(a) of the Act, Congress specifically has established resource limits for an individual's eligibility for the needs-based benefits in the SSI program in addition to income limits. As was stated above, promissory notes or installment sales contracts received from the sale of an excluded home are resources, as described in § 416.1201, as long as the owner has the legal right to liquidate or convert the resource to cash which could be used for support and maintenance. In general, while it is true that some resources may not be available to be used immediately to meet an individual's daily needs, Congress has recognized that such resources have value in that they can be sold or "cashed out" and the money

received can be used by the individual for his or her support and maintenance.

Comment: The commenter stated that the NPRM does not explain how the Agency will determine the value of a promissory note or similar installment sales contract.

Response: We provide general guidance on resource valuation procedures in paragraphs (b) and (c) of § 416.1201 of our regulations. These paragraphs explain how we evaluate liquid and nonliquid resources according to their equity value. For purposes of this evaluation, the equity value of a resource is defined as the price for which an item can reasonably be expected to sell on the open market in the particular geographic area involved minus any encumbrances. The value of a promissory note or installment sales contract will be determined by using this procedure.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this rule does not meet the criteria for a significant regulatory action under E.O. 12866. Thus, it was not subject to OMB review.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because this regulation affects only individuals and States. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act of 1980, is not required.

(Catalog of Federal Domestic Assistance Program No. 93.807, Supplemental Security Income).

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income.

Dated: July 5, 1994.

Shirley Chater,

Commissioner of Social Security.

Approved: August 16, 1994.

Donna E. Shalala,

Secretary of Health and Human Services.

For the reasons set out in the preamble, Part 416 of Chapter III of Title 20, Code of Federal Regulations, is amended as follows:

PART 416—[AMENDED]

1. The authority citation for Subpart L of Part 416 continues to read as follows:

Authority: Secs. 1102, 1602, 1611, 1612, 1613, 1614(f), 1621 and 1631 of the Social Security Act; 42 U.S.C. 1302, 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j and 1383; sec. 211 of Pub. L. 93–66; 87 Stat. 154.

2. Section 416.1212 is amended by redesignating the existing text in paragraph (d) as paragraph (d)(1), adding new paragraphs (d)(2) and (d)(3), and adding new paragraphs (e), (f) and (g) to read as follows:

§ 416.1212 Exclusion of the home.

* * * * *

(d) *Proceeds from the sale of an excluded home.*

(1) * * *

(2) The value of a promissory note or similar installment sales contract constitutes a "proceed" which can be excluded from resources if—

(i) The note results from the sale of an individual's home as described in § 416.1212(a);

(ii) Within 3 months of receipt (execution) of the note, the individual purchases a replacement home as described in § 416.1212(a) (see paragraph (e) of this section for an exception); and

(iii) All note-generated proceeds are reinvested in the replacement home within 3 months of receipt (see paragraph (f) of this section for an exception).

(3) In addition to excluding the value of the note itself, other proceeds from the sale of the former home are excluded resources if they are used within 3 months of receipt to make payment on the replacement home. Such proceeds, which consist of the downpayment and that portion of any installment amount constituting payment against the principal, represent a conversion of a resource.

(e) *Failure to purchase another excluded home timely.* If the individual does not purchase a replacement home within the 3-month period specified in paragraph (d)(2)(ii) of this section, the value of a promissory note or similar installment sales contract received from the sale of an excluded home is a countable resource effective with the first moment of the month following the month the note is executed. If the individual purchases a replacement home after the expiration of the 3-month period, the note becomes an excluded resource the month following the month of purchase of the replacement home provided that all other proceeds are fully and timely reinvested as explained in paragraph (f) of this section.

(f) *Failure to reinvest proceeds timely.* (1) If the proceeds (e.g., installment amounts constituting payment against the principal) from the sale of an excluded home under a promissory note or similar installment sales contract are not reinvested fully and timely (within 3 months of receipt) in a replacement home, as of the first moment of the month following receipt of the payment, the individual's countable resources will include:

(i) The value of the note; and

(ii) That portion of the proceeds, retained by the individual, which was not timely reinvested.

(2) The note remains a countable resource until the first moment of the month following the receipt of proceeds that are fully and timely reinvested in the replacement home. Failure to reinvest proceeds for a period of time does not permanently preclude exclusion of the promissory note or installment sales contract. However, previously received proceeds that were not timely reinvested remain countable resources to the extent they are retained.

Example 1. On July 10, an SSI recipient received his quarterly payment of $200 from the buyer of his former home under an installment sales contract. As of October 31, the recipient has used only $150 of the July payment in connection with the purchase of a new home. The exclusion of the unused $50 (and of the installment contract itself) is revoked back to July 10. As a result, the $50 and the value of the contract as of August 1, are included in a revised determination of resources for August and subsequent months.

Example 2. On April 10, an SSI recipient received a payment of $250 from the buyer of his former home under an installment sales contract. On May 3, he reinvested $200 of the payment in the purchase of a new home. On May 10, the recipient received another $250 payment, and reinvested the full amount on June 3. As of July 31, since the recipient has used only $200 of the April payment in connection with the purchase of the new home, the exclusion of the unused $50 (and of the installment contract itself) is revoked back to April 10. As a result, the $50 and the value of the contract as of May 1 are includable resources. Since the recipient fully and timely reinvested the May payment, the installment contract and the payment are again excludable resources as of June 1. However, the $50 left over from the previous payment remains a countable resource.

(g) *Interest payments.* If interest is received as part of an installment payment resulting from the sale of an excluded home under a promissory note or similar installment sales contract, the interest payments do not represent conversion of a resource. The interest is

income under the provisions of §§ 416.1102, 416.1120, and 416.1121(c).

[FR Doc. 94–20629 Filed 8–22–94; 8:45 am]
BILLING CODE 4190–29–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[VA9–7–5473; FRL–5052–4]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revised Good Engineering Practice Stack Height Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision establishes that the degree of emission limitation required for the control of any air pollutant is not affected by that portion of the stack height which exceeds good engineering practice (GEP) or by any other dispersion technique. The revision is consistent with the stack height provisions under EPA's "Requirements for Preparation, Adoption and Submittal of Implementation Plans—Control Strategy." The intended effect of this action is to approve a SIP revision consisting of a stack height regulation adopted by the Commonwealth of Virginia. This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule will become effective on September 22, 1994.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and Virginia Department of Environmental Quality, 629 East Main Street, P.O. Box 10089, Richmond, Virginia 23240.

FOR FURTHER INFORMATION CONTACT: Harold A. Frankford, (215) 597–1325.

SUPPLEMENTARY INFORMATION: On October 19, 1987 (52 FR 38787), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed approval of revisions to parts I, IV and V of Virginia's Regulations for the Control and Abatement of Air Pollution governing numerous revisions including good engineering practice (GEP) stack height provisions. No public comments were received on the NPR. The formal SIP revision had been submitted to EPA by Virginia on May 12, 1986. Virginia had adopted this regulation to conform to the July 8, 1985 promulgation of the revised GEP stack height regulation.

Virginia's SIP revision request consists of amendments to its regulations that restrict the degree to which industrial sources of air pollution may rely on dispersion pollution, using tall smoke stacks and other techniques as substitutes for constant emission controls.

Revisions to Part I—Definitions

Revised

Dispersion Technique, Elevated Terrain, Excessive Concentrations, GEP Stack Height, Nearby, Stack, Stack in Existence

Deleted

Elevated Terrain, Plume Impaction

Revisions to Part IV—Control of Emissions from Existing Sources

REVISED REGULATION: Section 120–02–04I.

The amended provisions reflect the revised the definition of the term "GEP stack height." The amended provisions also specifically exempt the following classes of sources:

1. Stack heights in existence as of 12/31/70, except where pollutants are being emitted or using dispersion techniques which were constructed, reconstructed, or carried out after 12/31/70.

2. Coal-fired steam electric generating units subject to the provisions of section 118 of the Clean Air Act, which commenced operation before 7/1/57, and whose stacks were constructed under a contract awarded before 2/8/74.

Revisions to Part V—New and Modified Sources

REVISED REGULATION: Section 120–05–02H.

EPA Evaluation

EPA has evaluated Virginia's SIP revision request and has concluded the following: (1) The GEP stack height requirements will not adversely affect Virginia's ability to enforce the currently applicable emission limits which adequately protect the national ambient air quality standards (NAAQS); (2) the GEP stack height requirements are clearly enforceable; and (3) the applicable requirements of 40 CFR part 51 have been met. A more detailed evaluation is provided in a Technical Support Document available upon request from the Regional EPA office listed in the **ADDRESSES** section of this document.

Final Action

EPA is approving Virginia's GEP stack height provisions submitted on May 16, 1986 as a revision to the Virginia SIP.

The Agency has reviewed this request for revision of the Federally-approved State implementation plan for conformance with the provisions of the 1990 amendments enacted on November 15, 1990. The Agency has determined that this action conforms with those requirements irrespective of the fact that the submittal preceded the date of enactment.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The OMB has exempted this regulatory action from E.O. 12866 review.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 24, 1994. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving Virginia's GEP stack height regulations may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 4, 1994.

Peter H. Kostmayer,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart VV—Virginia

2. Section 52.2420 is amended by adding paragraph (c)(91) to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(91) Revisions to the State Implementation Plan for the good engineering practice (GEP) stack height requirements submitted on May 12, 1986 by the Virginia State Air Pollution Control Board:

(i) Incorporation by reference.

(A) Letter of May 12, 1986 from the Executive Director, Virginia State Air Pollution Control Board, transmitting the revised good engineering practice (GEP) stack heights requirements.

(B) Revised Regulations 120–01–02 (Revised definitions of dispersion technique, elevated terrain, Excessive Concentrations, GEP Stack Height, Nearby, Stack, Stack in Existence), 120–04–02I, and 120–04–02H of the Virginia Regulations for the Control and Abatement of Air Pollution, adopted April 7, 1986, and effective June 6, 1986.

(C) Deletion of the following definitions from Regulation 120–01–02: Elevated Terrain, Plume Impaction

(ii) Additional material.

(A) Remainder of the official State submittal, transmitted on May 16, 1986.

* * * * *

[FR Doc. 94–20636 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 52

[OH16–2–6322; FRL–5053–4]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: On October 18, 1991, USEPA received proposed revisions to the emission limitations, compliance methodologies, and compliance time schedules in Ohio's Clean Air Act (Act) State Implementation Plan (SIP) for sulfur dioxide (SO_2) as it applies to sources in Hamilton County. These SIP revisions were submitted by the State of Ohio as a means of demonstrating attainment of the National Ambient Air Quality Standards (NAAQS) for SO_2. Subsequent revisions to the Hamilton County emission limits were received on March 19, 1993. The USEPA proposed to conditionally approve these SIP revisions on January 27, 1994. As discussed below, three comments were received on the proposed rulemaking. The USEPA is now granting conditional approval of the SIP revisions for SO_2 in Hamilton County, Ohio.

EFFECTIVE DATE: This final rule becomes effective on September 22, 1994.

ADDRESSES: Copies of the SIP revision, public comments on the rulemaking, and other materials relating to this final rule are available for inspection at the following address: (It is recommended that you telephone Randy Robinson, (312) 353–6713, before visiting the Region 5 Office.) United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard (AE–17J), Chicago, Illinois 60604.

A copy of this revision to the Ohio SIP is available for inspection at the following address: Air Docket 6102, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Randy Robinson, Air Enforcement Branch, Regulation Development Section (AE–17J), United States Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 353–6713.

SUPPLEMENTARY INFORMATION:

I. Background

On October 18, 1991, USEPA received a submittal from the State of Ohio to revise the SO_2 State Implementation Plan (SIP) for sources in Hamilton County. The submittal package included revisions to Ohio Administrative Code (OAC) 3745–18–03 Attainment dates and Compliance Time Schedules, (OAC) 3745–18–04 Measurements Methods and Procedures, and OAC 3745–18–37 Hamilton County Emission Limits, as well as technical information demonstrating that the revisions were sufficient to assure attainment of the National Ambient Air Quality Standards (NAAQS) for SO_2 in Hamilton County. Subsequent revisions to the Hamilton County emission limits, were submitted by Ohio to USEPA on March 17, 1993. The revisions were submitted in response to a December 22, 1988, letter in which USEPA notified the Governor of Ohio that the SIP for SO_2 was substantially inadequate to attain and maintain the SO_2 NAAQS in Hamilton County. The notification was based on predicted violations of the SO_2 National Ambient Air Quality Standards (NAAQS) due to SO_2 emissions from sources located in Hamilton County, Ohio.

II. Summary of Proposed Rulemaking

On January 27, 1994, a document was published in the **Federal Register** (59 FR 3809) which proposed conditionally approving the SIP revisions submitted by Ohio for Hamilton County. The proposed notice discussed the State submittal, including background information, the attainment demonstration, compliance methodologies, and the proposed rulemaking action.

A. Attainment Demonstration

The principal requirement for the Ohio SO_2 SIP under section 110 of the Act is that the plan provide sufficient enforceable measures to assure attainment of the NAAQS for SO_2. The State of Ohio provided enforceable limits in the form of State regulations, supplemented by an administrative order for one source, along with an air dispersion modeling analysis which demonstrated that these limits assure attainment in the Hamilton County area. The demonstration also relied on a non-Federally enforceable operation limit for an Indiana source. This issue is being resolved by the State of Indiana and is discussed later in this document.

The modeling techniques used in the attainment demonstration supporting this revision were based on procedures in the "Guideline on Air Quality Models (Revised)," July 1986, including "Supplement A," July 1987. The attainment demonstration incorporated air dispersion models which are appropriate for modeling sources of SO_2. The majority of the attainment demonstration was comprised of output from the Industrial Source Complex—Short Term (ISCST) air dispersion model; however, several areas of Hamilton County were modeled using the Rough Terrain Diffusion Model (RTDM). The appropriateness of the RTDM model for use in this application was determined through a "Model Evaluation and Comparison Study", conducted by the Greater Cincinnati Chamber of Commerce, in cooperation with the OEPA and USEPA, Region 5. Based on the results of the study, USEPA approved the RTDM model for use in modeling sulfur dioxide sources in Hamilton County in a June 9, 1992, letter from David Kee, Director, Air and Radiation Division, to Robert

Hodanbosi, Chief, Division of Air Pollution Control. The modeling demonstration accompanying the SIP revision submittal incorporated dispersion modeling output from both the ISCST model and the RTDM model. Background concentrations were added to the modeled concentrations for each averaging period, to produce overall maximum concentrations of 1296 μg/m³, 364 μg/m³, and 78 μg/m³, for the 3-hour, 24-hour, and annual averages, respectively. These values were compared against the 3-hour, 24-hour, and annual NAAQS concentrations of 1300 μg/m³, 365 μg/m³, and 80 μg/m³.

During the development of the attainment demonstration, a modeled violation was predicted near the Joseph E. Seagram and Sons, Inc. (Seagram's) facility in Dearborn County, Indiana. In response to this modeled violation, a commitment was obtained from Seagram's, communicated in a letter from Seagram's to both the OEPA and the Indiana Department of Environmental Management (IDEM), dated September 1, 1992, agreeing to not operate its two boilers simultaneously on sulfur-bearing fuels without written permission from both State Agencies. Utilizing this commitment, the OEPA submitted supplementary modeling which demonstrated that areas near Seagram's, in Indiana, did not exceed the sulfur dioxide NAAQS. However, in order for the Seagram's limit to be Federally enforceable, it must be incorporated into the Indiana sulfur dioxide SIP. Therefore, the Hamilton County SO_2 SIP revision is being approved conditioned on Seagram's commitment, described above, being proposed for adoption into the Indiana SO_2 SIP within one year from the date of publication of this Hamilton County SO_2 SIP revision final rulemaking. It is fully anticipated that the Indiana limit will be formalized in the allotted time and, as a result, the Ohio revised rules will remain a part of the SIP.

B. Compliance

The general compliance determination method denoted in OAC 3745–18–04(D)(7), which applies specifically to Hamilton County, utilizes stack gas sampling using Methods 1 through 4 and 6, 6A, 6B, or 6C, as specified in 40 CFR 60.46, for any fuel burning equipment. Additional compliance monitoring is required under OAC 3745–18–04(D)(8), which, on a source-specific basis, requires either daily or weekly coal sampling. The USEPA has determined, based on guidance contained in the "General preamble for future proposed rulemakings," published in the **Federal Register** on April 16, 1992 (57 FR 13498), that compliance methods 1 through 4, 6, 6A, 6B, and 6C, in conjunction with regular fuel sampling, provide for continuous SO_2 compliance monitoring. Additionally, documentation criteria listed in OAC 3745–18–04(I) requires sources subject to the Hamilton County emission limits to document and retain information needed to demonstrate compliance with applicable emission limits, emission tracking requirements, and/or operating limits.

III. Public Comment/USEPA Response

In response to the request for written comments on the proposed rulemaking, USEPA received two sets of comments. The first set of comments were received from Counsel for the Greater Cincinnati Chamber of Commerce SO_2 Task Force, in a letter dated February 25, 1994. The second set of comments were received from the Ohio Environmental Protection Agency, in a letter dated February 24, 1994. The following discussion summarizes the comments and USEPA's response.

Comment: The notice of proposed rulemaking stated that it was possible that future resolution of the U.S. D.C. Court of Appeals remand, involving USEPA stack height guidance, would result in the State of Ohio being required to revise the emission limitations for Unit 5 at the CG&E Miami Fort facility. Both OEPA and the Cincinnati Chamber of Commerce SO_2 Task Force commented that, due to the construction of a new 590-foot Good Engineering Practice (GEP) formula stack, which was shown to be necessary through a fluid modeling study, emission limitations at the CG&E Miami Fort Facility are not subject to revision pending resolution of the stack height remand court case. The Cincinnati Chamber of Commerce SO_2 Task Force requested that USEPA clarify this issue in the final rulemaking.

Response: In 1976, Miami Fort raised its Unit 5 stack from 70 meters to 87 meters. This was a within-GEP formula stack height increase which occurred between December 31, 1970, and October 11, 1983, and was not supported by a fluid modeling study. Consequently, this was an issue that fell into the scope of the D.C. stack height remand case. However, USEPA agrees that the resolution of the stack height remand case will not affect the within-GEP formula stack height increase issue involving Unit 5, since a fluid modeling study has subsequently been conducted to justify the construction of a new, 590-foot GEP stack which now serves Units 5 and 6. The wind tunnel fluid modeling study demonstrated that emissions from the older stacks at CG&E's Miami Fort Station Units 5 and 6 created excessive concentrations of SO_2 due to building induced downwash, therefore justifying the construction of the newer GEP stack.

Good Engineering Practice questions pertaining to Miami Fort Station Unit 7 were resolved in a December 10, 1992, letter from USEPA to OEPA, which concluded that the Unit 7 stack height was fully creditable, based on the determination that the stack had been "in existence" prior to December 31, 1970.

Comment: The OEPA and the Cincinnati Chamber of Commerce SO_2 Task Force also both requested that the approved rule incorporate a proposed variance for Procter and Gamble which would offer alternative emission scenarios pertaining to start-up and shut-down of 4 boilers.

Response: The proposed variances have not been submitted to USEPA as proposed SIP revisions. The USEPA is proceeding with final rulemaking on the rule revisions which have been formally submitted by the OEPA. The USEPA cannot approve a variance which has not been adopted or submitted by the State. The Procter and Gamble proposed rule revision, if and when submitted, will be dealt with through separate rulemaking.

Comment: The Cincinnati Chamber of Commerce SO_2 Task Force commented that the proposed conditional approval of the Hamilton County SIP revisions (conditional on the State of Indiana incorporating limits into its SO_2 SIP) is not necessary because of the commitment letter submitted by the Indiana source, which would limit them sufficiently to show attainment. Additionally, they commented that the limits in the letter could easily be incorporated into a title V permit for the source.

Response: It is necessary to condition the Hamilton County SO_2 SIP revision approval upon action to be taken by the State of Indiana because it is evident from the technical support that sources in Ohio, although not the major contributors, are significant contributors to modeled violations in Indiana. Subsequent modeling demonstrations, using the self-imposed limits on the Indiana source, show attainment. However, these limits can only support an attainment demonstration if they are Federally enforceable. The USEPA notified the State of Indiana, in a January 5, 1994 letter from Stephen Rothblatt, Chief, Regulation Development Branch, Region 5 to Timothy J. Method, Assistant

Commissioner, Office of Air Management, IDEM, that the Seagram's limits must be incorporated into the SO_2 SIP by April 1, 1995, or a notice of SIP deficiency will be issued. The IDEM responded in a letter dated June 27, 1994, that the Seagram's limits will be incorporated into Indiana's SO_2 rule for Dearborn County and submitted to USEPA as a SIP revision by April 1, 1995.

IV. Rulemaking Action

On January 27, 1994, USEPA proposed to conditionally approve revisions to the emission limitations, compliance methodologies, and compliance time schedules in Ohio's State Implementation Plan for sulfur dioxide (SO_2) for Hamilton County. The USEPA received two sets of comments pertaining to the proposed rulemaking. All of the comments were responded to in the above section of this document.

The USEPA concludes that the Ohio submittal will satisfy the requirements of section 110(a)(2) of the Act, once Indiana fulfills its commitment to incorporate the Seagrams limits into the Indiana SO_2 SIP. Therefore, USEPA is taking final action to conditionally approve the revisions to Ohio Administrative Code (OAC) rules 3745–18–03 Attainment Dates and Compliance Time Schedules, 3745–18–04 Measurement Methods and Procedures, and 3745–18–37 Hamilton County Emission Limits, as they apply to Hamilton County sources.

Under section 110(k)(4) of the Act, pertaining to conditional approval, the SIP elements regarding the Seagram's limits must be adopted by the State of Indiana and submitted to USEPA as a SIP revision, by a date not later than one year after the date of approval of this Hamilton County, Ohio SIP revision. In this case, if the State of Indiana fails to adopt or submit the necessary rules within the required time frame (September 23, 1995) or if USEPA disapproves the limits as a SIP revision, this approval would become a disapproval upon USEPA notification of Ohio by letter. The USEPA subsequently would publish a document announcing such action in the **Federal Register**. If the State of Indiana adopts and submits the rule within the above timeframe, the conditionally approved rules would remain a part of the Ohio SIP pending final action on the Indiana submittal.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. The USEPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. (5 U.S.C. 603 and 604.) Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

Conditional SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the Act, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

If the conditional approval is converted to a disapproval under section 110(k) of the Act, based on the State's failure to meet the commitment, it will not affect any existing state requirements applicable to small entities. Federal disapproval of the State submittal does not affect its state-enforceability. Moreover, USEPA's disapproval of the submittal would not impose a new Federal requirement. Therefore, USEPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing State requirements nor does it substitute a new Federal requirement.

This action makes final the action proposed at 59 FR 3809. The USEPA received no significant adverse public comment on the proposed action. The comments received did not object to the overall approvability of the proposed revisions. One comment requested that USEPA not condition the approval on actions to be taken by another State. However, there is agreement that the limits on the Indiana source are necessary and required for the Hamilton County attainment demonstration. The remainder of the comments requested clarifications and additional rulemaking. As a result of receiving no comments substantively adverse to the approvability of the Hamilton County SIP, the Regional Administrator has reclassified this action from Table 2 to a Table 3 under the processing procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and Table 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years. The USEPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. The OMB has agreed to continue the waiver until such time as it rules on USEPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 24, 1994. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Incorporation by reference, Reporting and record keeping requirements, Sulfur oxides.

Note—Incorporation by reference of the State Implementation Plan for the State of Ohio was approved by the Director of the **Federal Register** on July 1, 1982.

Dated: July 26, 1994.

Michelle D. Jordan,

Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart KK—Ohio

2. Section 52.1919 is added to read as follows.

§ 52.1919 Identification of plan-conditional approval.

(a)(1) On October 16, 1991, and March 17, 1993, the Ohio Environmental Protection Agency (OEPA) submitted revisions to the State Implementation Plan (SIP) for sulfur dioxide for sources in Hamilton County, Ohio. The revisions are approved provided that the State of Indiana Department of Environmental Management (IDEM) submits to USEPA, by September 23, 1995, a proposed SIP revision incorporating the limits identified in the September 1, 1992, letter from Joseph E. Seagram and Sons, Inc. to IDEM and the Ohio Environmental Protection Agency.

(i) Incorporation by reference.

(A) Ohio Administrative Code (OAC) Rule 3745–18–03 Attainment dates and compliance time schedules, Sections (A)(2)(c); (B)(7)(a); (B)(7)(b); (C)(8)(a); (C)(8)(b); (C)(9)(a); (C)(9)(b); (D)(1); (D)(2); dated October 11, 1991, and effective on October 31, 1991.

(B) Ohio Administrative Code (OAC) Rule 3745–18–04 Measurement methods and procedures, Sections (D)(7); (D)(8)(a) to D(8)(e); (E)(5); (E)(6)(a); (E)(6)(b); (F); (G)(1) to (G)(4); (I); dated October 11, 1991, and effective on October 31, 1991.

(C) Ohio Administrative Code (OAC) Rule 3745–18–37, Hamilton County sulfur dioxide emission limits, dated February 22, 1993, and effective on March 10, 1993.

(D) Director's Findings and Order for Cincinnati Gas And Electric Company, Miami Fort Station, dated February 22, 1993.

(b) [reserved].

[FR Doc. 94–20637 Filed 8–22–94; 8:45 am]
BILLING CODE 6560–50–P

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40 CFR Part 271

[FRL–5055–4]

North Carolina; Final Authorization of Revisions to State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate Final Rule, Affirmation.

SUMMARY: North Carolina has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). North Carolina's revisions consist of the Boilers and Industrial Furnaces Rule (BIF) promulgated February 21, 1991, the Technical Amendments for BIF promulgated July 17, 1991, and August 17, 1991, and the Administrative Stay promulgated September 5, 1991. The Environmental Protection Agency reviewed North Carolina's applications and published an Immediate Final Rule (IFR) on June 23, 1994, to authorize North Carolina for these revisions. EPA received several comments from the public on the IFR decision during the public comment period. This notice responds to those public comments and reaffirms the decision to grant North Carolina final authorization for the above-mentioned revisions.

EFFECTIVE DATE: Final authorization for North Carolina's program revisions shall be effective August 22, 1994.

FOR FURTHER INFORMATION CONTACT: Al Hanke, Chief, State Programs Section, Waste Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347–2234.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under Section 3006(b) of the Resource Conservation and Recovery Act ("RCRA" or "the Act"), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Public Law 98–616, November 8, 1984, hereinafter "HSWA") allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under Section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260–268 and 124 and 270.

On June 23, 1994, EPA published an Immediate Final Rule announcing its decision to grant North Carolina final authorization for revisions to its hazardous waste management program. Further background on the Immediate Final Rule to grant authorization appears at 59 FR 32377, June 23, 1994. Along with the Immediate Final decision, EPA announced the availability of the application and other materials for public comment.

Twelve (12) letters containing written comments were received during the public comment period. Most commenters expressed opposition to EPA's Immediate Final decision. Virtually all who opposed the decision objected because of concerns they have with North Carolina's largest commercial BIF. Individual letters containing responses to these facility specific concerns have been mailed to the commenters. Significant authorization issues raised by the commenters and EPA's responses are summarized below.

B. Comments/Response

Comment: Several commenters stated that Region IV had referred violations by BIF's to the North Carolina Department of Environment, Health, and Natural Resources (DEHNR) for enforcement, yet no enforcement action was taken on matters referred.

Response: EPA Region IV is not aware of any BIF violations for any facility in the State of North Carolina that were referred to DEHNR and in which DEHNR failed to take appropriate action. To date, EPA has not discovered any violations of the BIF rule at the commercial BIF mentioned by the commenters. As part of EPA's oversight role, a joint inspection with the State is scheduled for the facility in question in the near future.

Comment: Several commenters stated that North Carolina does not have adequate resources to administer the BIF requirements.

Response: EPA has thoroughly and carefully evaluated North Carolina's hazardous waste management program and is confident that North Carolina does in fact have the resources to administer the BIF requirements. North Carolina maintains a competent combustion permitting staff who are already actively involved in BIF permitting. North Carolina was one of the first States to accept responsibility for compliance inspections at small quantity burner facilities. The State maintains an on-site inspector program at commercial facilities, including the commercial BIF facility mentioned by commenters. North Carolina has already made significant progress in the implementation of the BIF rule. It should also be noted that North Carolina's regulatory authority for BIFs is identical to the federal authority. North Carolina adopts EPA hazardous waste regulations by reference. Therefore, North Carolina will enforce equivalent standards for BIFs within the State.

Comment: Several commenters stated that because North Carolina relies on a commercial BIF to meet its Capacity Assurance Plan (CAP), North Carolina DEHNR officials have indicated that this facility will obtain a BIF permit if North Carolina administers the program. The commenters felt that this prejudgment does not bode well for the State's willingness to act as a neutral regulator in the BIF permitting process.

Response: EPA's decision to grant North Carolina final authorization for the BIF rule does not constitute determination by the Agency or North Carolina on any permit application(s) pertaining to this facility. North Carolina included the facility in its Capacity Assurance Plan at the request of EPA. EPA requested North Carolina include all commercial capacity that was operating by the end of 1993 regardless of the facility's future status. North Carolina's CAP included all capacity the facility identified as coming on-line in the future. This does not reflect on North Carolina permitting intentions in any way.

C. Decision

After reviewing and responding to the public comments received on the initial Final Determination to authorize North Carolina for the BIF regulations, I affirm my conclusion that North Carolina's revisions meet all of the statutory and regulatory requirements established by RCRA. Accordingly, North Carolina is granted final authorization to operate its hazardous waste program as revised.

North Carolina now has responsibility for permitting treatment, storage, and disposal facilities within its borders and carrying out other aspects of the RCRA program described in its program revision application, subject to the limitations of HSWA, the Memorandum of Agreement, and this notice. North Carolina also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under Section 3007 of RCRA and to take enforcement actions under Section 3008, 3013, and 7003 of RCRA.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of North Carolina's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities.

This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended (42 U.S.C. 6912(a), 6926, 6974(b)).

Dated: August 12, 1994.

Winston A. Smith,

Acting Regional Administrator.

[FR Doc. 94–20686 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 300

[FRL–5050–5]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Final rule; notice of deletion of the Yakima Plating Company site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Yakima Plating Company site, located in Yakima, Washington from the National Priorities List (NPL). The NPL is Appendix B of the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). EPA and the State of Washington have determined that no further cleanup under CERCLA is appropriate and that the selected remedy has been protective of public health, welfare, and the environment.

EFFECTIVE DATE: August 23, 1994.

FOR FURTHER INFORMATION CONTACT: Sean Sheldrake, Site Manager, U.S. Environmental Protection Agency, Region 10, 1200 6th Avenue, HW–113, Seattle, WA 98101, (206) 553–1220.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is:

Yakima Plating Company, Yakima, Washington

A Notice of Intent to Delete for this site was published June 15, 1994, (59 FR 30752). The closing date for comments on the Notice of Intent to Delete was July 15, 1994. EPA received no comments.

EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund-financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425 of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede Agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and record keeping requirements, Superfund, Water pollution control, and Water supply.

Dated: July 15, 1994.

Gerald A. Emison,

Acting Regional Administrator, U.S. EPA Region 10.

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B [Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the site for Yakima Plating Co., Yakima, Washington.

[FR Doc. 94–20678 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 721

[OPPTS-50571A; FRL-4896-6]

Certain Aromatic Ether Diamines; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) which will require certain persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the following chemical substances for the uses identified in this preamble: Benzenamine, 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis- (CAS Number 94148-67-1, premanufacture notice (PMN) P-85-335); 1,2,4,5-benzenetetracarboxylic acid, diethyl ester, compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine] (1:1) (PMN P-85-336); and 1,2,4,5-benzenetetracarboxylic acid, 1,4-diethyl ester, compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine] (1:1), polymer with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine]-1,5-diethyl-1,2,4,5-benzenetetracarboxylate (1:1), reaction products with phthalic anhydride (CAS number 130097-33-5, PMN P-86-1153). These substances are identified generically as certain aromatic ether diamines. Hereinafter, these substances will be referred to by their respective PMN numbers. For P-85-336, the significant new use is any use; for P-85-335 and P-86-1153, the significant new uses are the manufacture, import, or processing in quantities of 100,000 pounds per year, or greater, and 225,000 pounds per year, or greater, respectively, for any use. EPA believes that this action is necessary because these chemical substances may be hazardous to human health and the uses identified in this rule may result in significant human exposures. The required notice will provide EPA with the opportunity to evaluate the intended use and associated activities, and an opportunity to protect against potentially adverse exposure before it can occur.

DATES: This rule becomes effective on October 6, 1994. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on September 6, 1994.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. E-545, Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This SNUR for P-85-335, P-85-336, and P-86-1153 requires persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of these substances for the significant new uses described in this final rule. The required notice will provide EPA with the information needed to evaluate an intended use and associated activities, and an opportunity to protect against unreasonable risks related to exposure to P-85-335, P-85-336, and P-86-1153 before it can occur. This rule was proposed in the **Federal Register** of May 30, 1990 (55 FR 21887). Since proposal, the TSCA Inventory chemical name for P-85-336 has been amended; the new name is used in this preamble. Additionally, the chemical substance 1,2,4,5-benzenetetracar-boxylic acid, 1,4-diethyl ester, compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis (oxy)]bis[benzenamine] (1:1), polymer with 4,4'-[[1,1'-biphenyl]-2,5-diylbis (oxy)]bis[benzenamine]-1,5-diethyl-1,2,4,5-benzenetetracarboxylate (1:1), the subject of PMN P-85-337, which was also included in the proposed SNUR, is not included in this final rule. EPA is not issuing a final SNUR on P-85-337 for reasons described in Unit V. of this preamble. This final rule serves to terminate the TSCA section 12(b) export notification requirements for P-85-337 that were triggered by the proposed SNUR. Finally, since proposal, the significant new use reporting triggers for P-85-335 and P-86-1153 have been waived as claims of confidential business information (CBI). These reporting triggers are now included in the regulatory text of this document.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent to which a use changes the volume of a chemical's production or to the type, form, magnitude, or duration of exposure to it. Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a significant new use notice (SNUN). If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Persons who import a chemical substance identified in a final SNUR must certify that they are in compliance with the SNUR requirements. The EPA policy in support of the importation certification appears at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the **Federal Register** of August 17, 1988 (53 FR 31252), EPA promulgated a "User Fee Rule" (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting SNUNs to submit certain fees to EPA are discussed in detail in that **Federal Register** document. Interested persons should refer to the CFR and the cited **Federal Register** document for further information.

III. Summary of This Rule

The chemical substances which are the subjects of this final SNUR are P-85-335, P-85-336, and P-86-1153. EPA is designating the manufacture, import, or processing of P-85-336 for any use as a significant new use. For P-85-335 and P-86-1153, EPA is designating the manufacture, import, or processing in quantities of 100,000 pounds per year, or greater, and 225,000 pounds per year, or greater, respectively, for any use as significant new uses. This rule requires persons intending to manufacture, import, or process the chemical substances

identified in this rule to submit a SNUN to EPA at least 90 days before they manufacture, import, or process these substances for the significant new uses described above. With regard to P–85–337, because EPA's concerns for the subject substances relate to the free diamine and P–85–337 has no free diamine, EPA has decided not to issue a final SNUR for P–85–337.

IV. Background Information on P–85–335, P–85–336, and P–86–1153

Background information on the regulatory history, production, use, health effects, and exposure for P–85–335, P–85–336, and P–86–1153 appears in the preamble to the proposed rule. Interested persons should refer to that document for further information.

V. Responses to Comments and Other Information Received Subsequent to SNUR Proposal

One company submitted comments in response to the proposed rule. In summary, the commenter believes that the proposed SNUR should be withdrawn because of the industrial hygiene practices associated with the substances' production, and the company's belief that the materials are made and used safely. Additionally, the commenter believes the proposed SNUR should be modified to reflect the absence of free diamine in P–85–337, and that processors and customer/users should be exempt from the SNUR requirements because of test data on P–85–335 and P–86–1153 that indicate dermal exposure does not cause retinotoxic effects.

EPA disagrees with the comment submitter that the proposed SNUR should be withdrawn in its entirety. Notwithstanding the status of the industrial hygiene practices associated with the substances' past or current production and use, EPA believes the designated significant new uses for P–85–335, P–85–336, and P–86–1153 may increase the magnitude and duration of exposure to the substances over that which currently exists. EPA's concerns regarding potentially significant human exposures that could be associated with the designated significant new uses and EPA's belief that the chemical substances may be hazardous to human health, provide more than an adequate basis for this rule.

As stated above with regard to P–85–337, because EPA's concerns for the subject substances relate to the free diamine and P–85–337 has no free diamine, EPA has decided not to issue a final SNUR for P–85–337.

Certain test data received from the commenter on P–85–335 and P–86–1153 subsequent to the subject SNUR proposal suggest that the substances are not likely to be absorbed through the skin in amounts sufficient to produce retinopathy in rats. These data indicate that a previous report of retinopathy following dermal administration of P–85–335 was compromised because the test animals were also orally exposed as a result of ingestion of the diamine from the application site. Based on these data, the commenter argues that dermal exposure is not a problem and asks that processors and users be exempted from the SNUR. EPA believes such an action would be inappropriate. Exposures to the subject substances during processing and use could potentially occur by inhalation or orally, as well as by the dermal route. Consideration and analysis of the potential routes of exposure associated with any significant new use would be part of the SNUN review process. Any regulatory follow-up action taken in response to a SNUN would take into account exposures, or lack thereof, associated with the processing or use of a substance. (It should be noted that only manufacturers, importers, and processors are subject to SNURs; chemical substance users who are not also manufacturers, importers, or processors are not subject to the SNUR notification provisions.)

The commenter also questioned EPA's use, in the preamble of the proposed rule, of a structure-activity analogy between P–85–335 and nitrofen (CAS Number 1836–75–5) to support a concern for developmental toxicity for the subject substances. In support of its position, the commenter cited a study on unchlorinated and monochlorinated nitrofen analogues where teratogenicity was either greatly reduced or absent as compared to nitrofen (Francis, *Toxicology* 40:297–309 (1986)). Additionally, the commenter cited a study that indicated both the number and position of chlorine substitutes had an effect on potential teratogenicity, although no simple structural relationship was found between position of chlorine substitutes and the effect (Francis, *Teratology* 41:443–51 (1990)).

EPA believes that the Francis studies, by themselves, are inadequate to discount the potential developmental toxicity of the subject substances. This 1986 study used too few animals per dose group (8–13), whereas an adequate developmental toxicity study generally requires 20 pregnant animals, and the highest dose tested for each nitrofen analogue was insufficient to produce maternal toxicity.

Also, the study evaluated effects using only one mammalian species, the mouse. According to EPA's Guidelines for Developmental Toxicity Risk Assessment (56 FR 63798), the minimum evidence to determine that an agent is unlikely to pose a hazard for developmental toxicity would generally include data from appropriate, well-executed laboratory animal studies in several species (at least two) which evaluated a variety of the potential manifestations of developmental toxicity and showed no adverse developmental effects at doses that were minimally toxic to the adult animal.

Regarding EPA's rationale for issuing the SNUR, the comment submitter disagreed with EPA's statement in the preamble to the proposed rule that the subject substances are currently subject to no regulation that would require notification to the Federal Government of activities that might result in adverse exposures to the substances, or provide a regulatory mechanism that could protect human health or the environment from potentially adverse exposures before they occurred. The commenter stated that EPA and OSHA have exercised their current regulatory authority over these compounds through existing laws, site audits, and information gathering. Notwithstanding this, the commenter did not point to any regulatory mechanism that currently mandates prior notification to the Federal Government of activities associated with the subject substances that may result in new adverse exposures and that provides the opportunity to prevent such exposures before they occur.

Finally, the commenter believes that because EPA has not evaluated all chemicals that may compete with the subject substances to the same extent as the subject substances, EPA should not issue the final SNUR. EPA disagrees. EPA is not required to evaluate all substances that may compete with a chemical substance before taking a SNUR action on that chemical substance. As discussed in the preamble to the proposed rule, EPA received information under TSCA section 8(e) on P–85–335. This information triggered EPA's review of P–85–335, as well as P–85–336, P–85–337, and P–86–1153 because of their structural relationship to P–85–335. EPA has not received information indicating a potential substantial risk on materials known to compete with the subject substances. The Agency believes it is not required to direct equal resources to evaluating a substance solely on the basis that it competes with another substance receiving regulatory attention. EPA is

taking action on this substance due to section 8(e) reports received by the Agency indicating possible risk.

VI. Objectives and Rationale for This Rule

To determine what would constitute a significant new use of P–85–335, P–85–336, and P–86–1153, EPA considered relevant information on the toxicity of the chemical substances, likely exposures associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new uses that are designated in this rule. EPA wants to ensure that:

(1) The Agency will receive notice of any company's intent to manufacture, import, or process P–85–335, P–85–336, and P–86–1153 for a significant new use before that activity begins.

(2) The Agency will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing P–85–335, P–85–336, and P–86–1153 for the significant new use.

(3) The Agency will be able to regulate prospective manufacturers, importers, or processors of P–85–335, P–85–336, and P–86–1153 before a significant new use of those substances occurs, provided that the degree of potential health and environmental risk is sufficient to warrant such regulation. Currently, P–85–335, P–85–336, and P–86–1153 are subject to no regulation that requires prior notification to the Federal Government of activities that might result in new adverse exposures to these substances, or provides a regulatory mechanism that could protect human health or the environment from potentially adverse exposures, before they occur.

EPA has received no TSCA section 5 Notice of Commencement of Manufacture for P–85–336 and therefore concludes that there is no ongoing commercial use of the substance. EPA believes that any use of P–85–336 may increase the magnitude and duration of exposure to the substance over that which currently exists. In light of the toxicity/potential toxicity of P–85–336, and for EPA to have the opportunity to evaluate any intended use and potential exposures associated with such use before that activity begins, EPA is designating "any use" as a significant new use for P–85–336. EPA believes that it is appropriate to designate "any use" as a significant new use for P–85–336 because a substantial period of time (more than 9 years) has elapsed since the original PMN submission, the substance has not been manufactured or imported commercially during that time, and the section 8(e) data were received well after PMN review ended.

The significant new uses being designated for both P–85–335 and P–86–1153 are manufacture, import, or processing in volumes of 100,000 pounds per year, or greater, and 225,000 pounds per year, or greater, respectively, for any use. These significant new uses, determined on a company-specific basis, represent a substantial increase in the ongoing manufacture, import, or processing volumes. EPA has determined that the manufacture, import, or processing of P–85–335 and P–86–1153 at levels at or above the volumes designated as significant new uses could significantly increase the magnitude and/or duration of human exposure to these substances over that which currently exists. EPA believes exposures to these chemical substances associated with manufacturing, importing, processing, use and associated activities could increase should manufacturing, importing, or processing volumes equal or exceed the volumes designated as significant new uses. EPA considers it is necessary to review chemical manufacture, import, or processing associated with new uses to ensure EPA has an opportunity to protect against potentially adverse exposure before it can occur. Further discussion of the rationale on which EPA bases its significant new use determinations for P–85–335 and P–86–1153 will not be included in this rule as it is derived from information claimed as CBI. A sanitized copy of the document describing the rationale for the significant new use determinations is available in the public record for this rule.

Given the toxicity and/or potential toxicity of these substances, the reasonably anticipated situations that could result in exposure, and the lack of sufficient regulatory controls, individuals could be exposed to P–85–335, P–85–336, and P–86–1153 at levels which may result in unreasonable risks. For the foregoing reasons, EPA is designating significant new uses for P–85–335, P–85–336, and P–86–1153 as set forth in § 721.825(a)(2), (a)(3), and (a)(4) of the regulatory text.

VII. Alternatives

In the proposed SNUR, EPA considered alternative regulatory actions for P–85–335, P–85–336, and P–86–1153, including a section 8(a) reporting rule and a section 6 rule. For the reasons discussed in the preamble to the proposed rule and elsewhere herein, EPA has decided to proceed with the promulgation of a SNUR for these chemical substances.

VIII. Applicability of Rule to Uses Occurring Before Effective Date of The Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the effective date of the final rule. If uses begun during the proposal period of a SNUR were considered ongoing as of the effective date, it would be difficult for EPA to establish SNUN requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, arguing that the use is no longer new.

Persons who began commercial manufacture, importation, or processing of P–85–335, P–85–336, and P–86–1153 for the significant new uses described in this rule between May 30, 1990, the date of the proposal, and the effective date of this SNUR were notified in the proposal that they must cease that activity before the effective date of this rule. An exception to this general requirement appears at § 721.45(h). If a person met the conditions of advance compliance as codified at § 721.45(h), the person will be considered to have met the requirements of the final SNUR for those activities. If persons who began commercial manufacture, importation, or processing of the chemical substance subject to the SNUR between proposal and the effective date of the SNUR have not met the conditions of advance compliance, they are required to cease that activity before the effective date of the rule. To resume their activities, these persons must comply with all applicable SNUN requirements and wait until the notice review period, including all extensions, expires.

IX. Test Data and Other Information

EPA recognizes that under TSCA section 5, persons are not required to develop any particular test data before submitting a SNUN. Rather, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them.

However, in view of the potential health risks that may be posed by a significant new use of P–85–335, P–85–336, and P–86–1153, EPA suggests potential SNUN submitters consider conducting tests that would permit a reasoned evaluation of risks posed by P–85–335, P–85–336, and P–86–1153 when utilized for an intended use.

SNUNs submitted without accompanying test data may increase the likelihood that EPA would take action under section 5(e).

EPA encourages persons to consult with EPA before selecting a protocol for testing P–85–335, P–85–336, and P–86–1153. As part of this optional pre-notice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the chemical substance. Test data should be developed according to TSCA Good Laboratory Practice Standards at 40 CFR part 792. Failure to do so may lead EPA to find such data to be insufficient to evaluate reasonably the health or environmental effects of the chemical substance.

EPA urges SNUN submitters to provide detailed information on human exposure or environmental release that may result from the significant new use of P–85–335, P–85–336, and P–86–1153. In addition, EPA encourages persons to submit information on potential benefits of the chemical substance and information on risks posed by the chemical substance compared to risks posed by potential substitutes.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for P–85–335, P–85–336, and, P–86–1153. EPA believes that costs imposed by the promulgation of this SNUR are not significant. There are no known producers other than the PMN submitters. Agency costs can be divided into three components: Issuing the SNUR, which has a cost of $12,233 to $23,790; reviewing the SNUN, which has a cost of $9,650; and modifying the SNUR, which has a cost of $10,323. Direct and indirect costs to industry are uncertain, in some instances too uncertain to estimate. The Agency estimates that the costs incurred by industry would be those involved in submitting a SNUN, which are estimated to be $2,133 to $10,323 per notice, as well as the related costs due to delays in initiating the production and use of a chemical. EPA's complete economic analysis is available in the public record for this rule (OPPTS–50571A).

XI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50571A). A public version of the record, without any CBI, is available in the TSCA Nonconfidential Information Center (NCIC), also known as, TSCA Public Docket Office, from 12 noon to 4 p.m., Monday through Friday, except legal holidays. NCIC is located in Rm. NE–B607, 401 M St., SW., Washington, DC 20460. The record includes the following basic information considered by the Agency in developing this rule:

(1) USEPA, "Certain Aromatic Ether Diamines; Proposed Significant New Uses of Chemical Substances." (May 30, 1990, 55 FR 21887).

(2) USEPA, "Certain Aromatic Ether Diamines; Proposed Significant New Uses of Chemical Substances." Extension of Comment Period. (July 9, 1990, 55 FR 28063).

(3) USEPA, OPPT, EETD. Economic Analysis of Proposed Significant New Use Rule for Certain Aromatic Ether Diamines. (October 1989).

(4) Comments received in response to rule proposal. The following (5–19) are submissions received under TSCA 8(e). (8EHQ–1085–0571 S *et seq.* submissions for Aromatic Ether Diamines.)

(5) Letter with attached notice of October 21, 1985, relating to subchronic inhalation study of an aromatic diamine. (November 18, 1985).

(6) Additional information to be used by EPA in evaluating aromatic diamines (January 10, 1986).

(7) Response to letter of December 10, 1985, requesting confidentiality substantiation for a submission (January 10, 1986).

(8) Final report on the 2–week inhalation study of aromatic diamine (February 14, 1986).

(9) Industrial hygiene monitoring study on aromatic diamine dated September 4, 1986 (September 12, 1986).

(10) Ocular pathology and skin irritation studies with aromatic diamine (January 26, 1987).

(11) Summary of Acute Toxicity Studies with Aromatic Diamine (March 5, 1987).

(12) Ocular toxicity produced by the aromatic diamine following acute dermal and inhalation exposure in rats and acute oral exposure in rabbits (May 22, 1987).

(13) Letter regarding studies with aromatic diamines (November 15, 1988).

(14) Copies of labels for aromatic ether diamine and mixtures containing the chemical (January 17, 1989).

(15) Waiver of confidentiality claim by DuPont (June 16, 1989).

(16) Results of additional studies with aromatic ether diamine (September 16, 1989).

(17) Ocular Pathology in Rats After Dermal Application of 2-Phenyl-APB-144 (July 29, 1991).

(18) Ocular Pathology in Rats After Dermal Application of Avimid K Prepreg (July 29, 1991).

(19) Final Report. 2-Phenyl-APB-144: Species Comparisons of In Vitro Skin Penetration Following a Single Application to the Excised Skin of Humans, New Zealand White Rabbits and CD1B Rats. (April 14, 1994).

(20) Letter from DuPont waiving busines confidentiality claims for the proposed SNUR production trigger volume limits (August 8, 1994).

XII. Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or, (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of this Executive Order, it has been determined that this rule is not "significant" and is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA expects to receive few SNUNs for the substances. Therefore, the Agency believes that the number of small businesses affected by the rule would not be substantial, even if all of the SNUN submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in the rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.*, and has assigned OMB

control number 2070–0038 for P–85–335 and P–86–1153 and OMB control number 2070–0012 for P–85–336, which has not yet been produced commercially.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements, Significant new uses.

Dated: August 15, 1994.

Joseph A. Carra,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By adding new § 721.825 to subpart E to read as follows:

§ 721.825 Certain aromatic ether diamines.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The following chemical substances are subject to reporting under this section for the significant new uses described in paragraphs (a)(2), (a)(3), and (a)(4) of this section: Benzenamine, 4,4′-[[1,1′-biphenyl]-2,5-diylbis(oxy)]bis- (CAS Number 94148–67–1, Premanufacture notice (PMN) P–85–335); 1,2,4,5-benzenetetracarboxylic acid, diethyl ester, compound with 4,4′-[[1,1′-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine] (1:1) (PMN P–85–336); and 1,2,4,5-benzenetetracarboxylic acid, 1,4-diethyl ester, compound with 4,4′-[[1,1′-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine] (1:1), polymer with 4,4′-[[1,1′-biphenyl]-2,5-diylbis(oxy)]bis[benzenamine]-1,5-diethyl-1,2,4,5-benzenetetra carboxylate (1:1), reaction products with phthalic anhydride (PMN P–86–1153).

(2) The significant new use for P–85–335 is: Manufacture, import, or processing in a quantity of 100,000 pounds per year, or greater, for any use.

(3) The significant new use for P–85–336 is: Any use.

(4) The significant new use for P–86–1153 is: Manufacture, import, or processing in a quantity of 225,000 pounds per year, or greater, for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* Section 721.5 applies to this section except § 721.5(a)(2). A person who intends to manufacture, import, or process for commercial purposes a substance identified in paragraph (a)(3) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

[FR Doc. 94–20688 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 7077

[AZ–930–4210–06; AZA–13398, AZA–13401, AZA–13402]

Partial Revocation of Secretarial Orders dated July 2, 1902, March 14, 1929, and September 30, 1904; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order partially revokes three Secretarial orders insofar as they affect 51.66 acres of public land withdrawn for the Bureau of Reclamation's Colorado River Survey, and the Colorado River Storage and Yuma Projects. The land is no longer needed for the purpose for which it was withdrawn, and the revocation is needed to permit disposal of the land through the Bureau of Land Management's land exchange program. This action will open the land to surface entry and mining, unless closed by overlapping withdrawals or temporary segregations of record. The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: September 22, 1994.

FOR FURTHER INFORMATION CONTACT: John Mezes, BLM Arizona State Office, P.O. Box 16563, Phoenix, Arizona 85011, 602–650–0509.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988) as amended, it is ordered as follows:

1. The Secretarial Orders dated July 2, 1902, March 14, 1929, and September 30, 1904, which withdrew land for the Bureau of Reclamation's Colorado River Survey, and the Colorado River Storage and Yuma Projects, are hereby revoked insofar as they affect the following described land:

Gila and Salt River Meridian

T. 9 S., R. 23 W.,
Sec. 29, lot 2, and SE¼SW¼.

The area described contains 51.66 acres in Yuma County.

2. At 10 a.m. on September 22, 1994, the land will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 10 a.m. on September 22, 1994 shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 10 a.m. on September 22, 1994 the land will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: August 11, 1994.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 94–20576 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 931199–4042; I.D. 081694B]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for groundfish, other than demersal shelf rockfish (DSR) in the Southeast Outside district, by vessels using hook-and-line gear in the Gulf of Alaska (GOA). This action is necessary because the entire bycatch allowance of Pacific halibut apportioned to hook-and-line gear in the GOA for the 1994 fishing year has been reached.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), August 31, 1994, until 12 midnight, A.l.t., December 31, 1994.

FOR FURTHER INFORMATION CONTACT: Michael L. Sloan, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the GOA (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

In accordance with § 672.20(f)(1)(ii), the 1994 Pacific halibut bycatch allowance for hook-and-line gear for groundfish fisheries in the GOA, other than DSR in the Southeast Outside district, was established by the final 1994 groundfish specifications (59 FR 7647, February 16, 1994) as 740 metric tons.

The Director, Alaska Region, NMFS, has determined, in accordance with § 672.20(f)(3)(ii)(A), that the catch of Pacific halibut by operators of vessels using hook-and-line gear in groundfish fisheries other than the directed fishery for DSR in the Southeast Outside District has reached the annual bycatch allowance of Pacific halibut. Therefore, NMFS is prohibiting directed fishing for groundfish, other than DSR in the Southeast Outside district, by vessels using hook-and-line gear in the GOA from 12 noon, A.l.t., August 31, 1994, until 12 midnight, A.l.t., December 31, 1994.

Directed fishing standards for applicable gear types may be found in the regulations at § 672.20(g).

Classification

This action is taken under 50 CFR 672.20 and is exempt from OMB review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 18, 1994.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–20677 Filed 8–22–94; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 59, No. 162
Tuesday, August 23, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

Reexamination of the NRC Enforcement Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; Request for public comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is reexamining its enforcement program and requests public comment on whether the scope, purpose, procedures, and methods of its enforcement program are appropriate, and how they may be improved. The NRC is soliciting comments from interested public interest groups, the regulated industry, states, and concerned citizens. Comments from both reactor and materials licensees are requested. This request is intended to assist the NRC in a review of its enforcement program which is being conducted to make recommendations for improvements in the regulatory process.

DATES: The comment period expires October 24, 1994. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to: David Meyer, Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publication Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. After September 1, 1994, it is expected that comments may also be provided electronically by accessing the NRC bulletin board system (BBS) that is a subsystem of FedWorld, which is operated by the National Technical Information Service. The NRC BBS can be accessed directly by a toll free number, (800) 303–9672, at modem speeds up to 9600 Baud with communication parameters set at 8 data bits, no parity, 1 stop bit, full duplex, and ANSI terminal emulation. Select the "Subsystems/Databases" option from the "NRC Main Menu" and then the "Enforcement Program" option. The "Help/Information Center" from the "Enforcement Program Menu" provides selections on "Request for Comments on the Enforcement Policy" and "How to Leave an Official Comment." The NRC BBS can also be accessed from the FedWorld "Subsystems/Databases" menu, which could facilitate user access using the Internet. FedWorld's access via Internet is Telnet access: fedworld.gov (192.239.92.3); FTP site access: ftp.fedworld.gov (192.239.92.205), and World Wide Web (Home Page): www.fedworld.gov (this is the URL).

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 504–2741. Questions on the NRC BBS may be directed to Tom Dunning at (301) 504–1189.

SUPPLEMENTARY INFORMATION: On May 13, 1994, the Executive Director for Operations directed a Review team composed of Senior NRC managers to reexamine the NRC enforcement program. The Review Team is chaired by James Lieberman, Director, Office of Enforcement, and includes James Fitzgerald, Acting Director, Office of Investigations, Roy Zimmerman, Associate Director for Projects, Office of Nuclear Reactor Regulations, William Brach, Deputy Division Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, Luis Reyes, Deputy Administrator Region II, and Jack Goldberg, Deputy Assistant General Counsel for Enforcement.

The purpose of this review effort is to (i) perform an assessment of the NRC's enforcement program to determine whether the defined purposes of the enforcement program are appropriate, (ii) determine whether the NRC's enforcement practices and procedures for issuing enforcement actions are consistent with those purposes, and (iii) provide recommendations on any changes the Review Team believes advisable. It is expected that the Review Team will complete its review and issue its report, including recommendations, by the end of January 1995.

The NRC's enforcement program is guided by the Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy). The Enforcement Policy is published in the Code of Federal Regulations at 10 CFR part 2, appendix C to provide widespread dissemination of the Commission's Enforcement Policy. However, it is a policy statement and not a regulation. The Enforcement Policy notes that the Commission, as appropriate under the circumstance of a particular case, can deviate from it.

The Commission's Enforcement Policy was first published in 1980 as an interim policy. 45 FR 66754 (October 7, 1980). On March 9, 1982 (47 FR 9987), the Commission published a final version of the policy. Since that time, the Enforcement Policy has been modified on a number of occasions to address changing requirements and additional experience. The current Enforcement Policy is reflected in the 1994 Code of Federal Regulations as supplemented by a July 15, 1994 (59 FR 36026), modification to provide additional severity level examples.

Since the Enforcement Policy was first promulgated, the purpose and the four objectives for the NRC enforcement program have remained essentially unchanged. Section I of the Enforcement Policy states that:

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by [the following four objectives]:

- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
- Deterring future violations and occurrences of conditions adverse to quality; and
- Encouraging improvement of licensee and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

In summary, the Enforcement Policy provides for a graduated set of sanctions based on the severity of the violations. Normally, each violation or grouping of violations is categorized into one of five severity levels based on the relative importance of the violation, including both the technical significance, i.e. the actual and potential consequences, and the regulatory significance including any willfulness associated with the violation. Formal sanctions include Notices of Violations, civil penalties, and orders. In determining the particular sanction to be used, consideration is given to (i) the severity level of the violation, including its duration, (ii) the licensee's response to the violation, including whether the licensee identified the violation and corrected it, and (iii) the licensee's past performance, including whether the violation was a recurring one, the licensee's compliance history and general performance, and whether there were prior opportunities to discover, correct, or avoid the violation. The Enforcement Policy provides for the ability to exercise discretion to increase or reduce sanctions (including dispositioning certain violations as non-cited violations) to provide appropriate regulatory messages to encourage improved performance. Enforcement actions involving orders or violations at Severity Level I, II, or III are considered more significant and are referred to as escalated actions. In addition to formal enforcement sanctions, NRC also uses administrative actions such as Demands for Information, Confirmatory Action Letters, and Letters of Reprimand.

In accordance with its charter, the Review Team, is to consider, but not be limited to, the following issues in conducting its assessment of the enforcement program:

(i) The balance between providing deterrence and incentive (both positive and negative) for the identification and correction of violations,

(ii) The appropriateness of NRC sanctions,

(iii) Whether the Commission should seek statutory authority to increase the amount of civil penalties,[1]

(iv) Whether there should be different enforcement policies and practices for material licensees in contrast to power reactors or large fuel facilities, and

(v) Whether the Commission should establish open enforcement conferences as the normal practice.[2]

Public comments are sought on these issues to assist the Review Team in its reassessment. In addition to general comments on the above issues, the Review Team seeks comments on a number of specific issues.

Comments are sought from both reactor and material licensees, vendors, other persons who are subject to NRC enforcement jurisdiction, state and local governments, and other members of the public who may have an interest in NRC enforcement actions. Although the Review Team is interested in as many comments as possible, commenters are not obligated to and need not address every issue.

In providing comments, please key comments to the numbering system used to identify the specific issues by providing the issue number before the particular comment (e.g., Response to A.3). General or anecdotal comments (such as a general comment to the effect that some enforcement conferences have not been effective or that some enforcement cases have been inconsistent with the Enforcement Policy) will not be particularly useful. Rather comments should be as specific as possible and should reference specific cases, as appropriate, so that the Review Team can understand and evaluate the comment. Responses which call for a "yes" or "no" answer should be accompanied with an explanation as to why the commenter agrees or disagrees with the issue. When the term licensee is used in the issues listed below, it refers, as applicable, to licensees, vendors, and other persons subject to NRC enforcement actions.

Comments may be provided in hard copy or through the NRC electronic bulletin board(BBS). Instructions for accessing the NRC BBS are provided in the ADDRESSES section above.

Following evaluation of the comments, the Review Team may hold a public meeting in the Washington, D.C. area for the purpose of clarifying comments. In that regard, commenters are requested to indicate whether they would desire to participate in a public meeting. It is expected that the Review Team would invite specific commenters to participate on panels of commenters with similar views. If a meeting is to be held, it will be announced in the **Federal Register** and on the NRC BBS.

Comments are requested on the following specific issues:

A. Purpose and Objectives of the NRC Enforcement Program

1. Is the purpose of the enforcement program stated above the proper area of focus for the NRC enforcement program? If not, why not and what should the purpose be?

2. Are the four objectives of the NRC enforcement program stated above (i.e., ensuring compliance, obtaining corrective action, deterring future violations, and encouraging improved performance of other licensees and vendors) appropriate? If not, why not and what should the objectives be?

3. Does the enforcement program as implemented achieve the stated purpose and objectives? Explain why or why not.

(a) Are enforcement sanctions effective in obtaining comprehensive and lasting corrective action, i.e., does the time and effort spent in developing responses to enforcement actions result in a more thought out approach for corrective action and implementation of that action than would otherwise occur?

(b) Do some types of sanctions result in more extensive, comprehensive, or lasting corrective action than others?

(i) If so, which types of sanctions are more effective than others, i.e., (a) Notices of Violation at Severity Level V, at Severity Level IV with and without a civil penalty, at Severity Level III with and without a civil penalty, at Severity Level II with and without a civil penalty, and at Severity Level I with and without a civil penalty, and (b) orders?

(ii) If so, why? For example, do some sanctions get more management attention than others, i.e., do all senior licensee officials, such as the Vice Presidents, President, Chief Executive Officer or Board of Directors, get copies of every sanction including non-cited violations, or do senior officials only get copies of certain types of sanctions such as civil penalties or orders, or for that matter do they get copies at any time?

(iii) If not, what changes could be made to improve corrective action?

(c) Has the NRC's past use of sanctions created deterrence, i.e., does the threat of sanctions contribute to the desire to maintain compliance?

[1] In 1993, the Commission conducted a reassessment of the NRC's program for protecting allegers against retaliation. The Review Team which performed that reassessment recommended, among other things, that the NRC should seek an amendment to section 234 of the Atomic Energy Act of 1954 to increase the current maximum civil penalty of $100,000 to $500,000 per day per violation to be normally used for willful violations including those involving discrimination. Recommendation II.D–3, "Reassessment of the NRC's Program for Protecting Allegers Against Retaliation," NUREG–1499 (January 1994). The Commission did not act on this recommendation, but instead, the Commission approved a staff proposal to defer action on the recommendation pending a review of the NRC Enforcement Program.

[2] In 1992, the NRC established a two-year trial program for conducting enforcement conferences open to attendance by members of the public (57 FR 30762, July 10,1992). This trial program was to end July 11, 1994 upon which date comments were due on whether NRC should routinely conduct open enforcement conferences. However, in light of the reexamination of the enforcement program, the trial program was extended pending the outcome of the enforcement program review (59 FR 36796, July 19,1994).

(i) If not, what changes could be made to provide more deterrence?

(ii) Commenters are requested to address the deterrence value of each type of sanction: (a) Notices of Violation at Severity Level V, at Severity Level IV with and without a civil penalty, at Severity Level III with and without a civil penalty, at Severity Level II with and without a civil penalty, and at Severity Level I with and without a civil penalty, and (b) orders.

(iii) To what extent does the issuance of press releases contribute to the deterrence?

(iv) Should press releases be issued for Notices of Violation, Confirmatory Action Letters, Demands for Information as well as civil penalties and orders? If not, why not?

(d) Do NRC sanctions against particular licensees result in improving the general performance of the regulated industry by encouraging other licensees to take actions to prevent or identify and correct similar violations at their facilities after learning of the violations and sanctions imposed on other licensees?

(i) Licensee commenters should address whether they are normally aware of enforcement actions issued against other licensees at the level of (1) non-escalated Notices of Violations, (2) escalated Notices of Violations without civil penalties, (3) civil penalties, and (4) orders.

(ii) If commenters are aware of enforcement actions issued against other licensees, how do they become aware of them (e.g, NUREG 0940, "Enforcement Actions: Significant Actions Resolved," NRC Information Notices, NMSS Newsletters, press releases, law firm news letters, industry newsletters such as Inside NRC or Nucleonics Weekly, NRC inspectors, **Federal Register**, or other sources)? Should NRC consider better ways to provide licensees and vendors with information about NRC enforcement actions such as use of an electronic bulletin board or an enforcement newsletter?

(iii) If commenters are aware of enforcement actions issued against other licensees, is the information from those actions used to improve performance? How is it used to achieve better performance (e.g., discussed during staff meetings, incorporated into training, or made the subject of required reading)?

4. Agency-wide (i.e., from region to region) consistency and predictability in the nature and type of sanctions have been important considerations in developing enforcement sanctions. As a result, the Enforcement Policy has become substantially more detailed since the initial policy was published in 1980. While flexibility is provided, deviations from the norms of the Enforcement Policy require approval or consultation with senior NRC officials, and in some cases, the Commissioners.

(a) If the enforcement program as implemented does not provide an appropriate degree of consistency and predictability, what are the problem areas and what changes could be made for improvement in this area?

(b) Should the Enforcement Policy be simplified and allow for more staff judgement and issuance of enforcement actions with less management review? If so, provide examples where changes could be made. If so, why and how?

5. When developing enforcement sanctions, how should the NRC attempt to balance punishment and incentives? [Note: this question addresses issuance of sanctions in general, questions on issuance of civil penalties are addressed in section E. of this notice.] Comments are requested on whether the remedial value of enforcement would be improved by:

(a) Basing sanctions solely on the occurrence of the violation and its technical and regulatory significance to maximize the incentive to discourage violations from occurring. Under this approach, in formulating a sanction, NRC would consider whether the violation occurred, but would not consider whether the licensee identified the violation and corrected it and would not consider the licensee's past performance, i.e., some or all sanctions would be issued somewhat like a traffic ticket. For example, an overexposure would have a fixed penalty for a given type of licensee. Commenters who favor this approach should address the question of whether this approach would tend to discourage licensees and employees from identifying violations that are not self disclosing and broadly correcting violations as those actions would not affect the sanction.

(b) Basing sanctions solely on the licensee's response to the violation. Under this approach, NRC would not issue a sanction if the licensee promptly identified, reported it if required, and promptly and comprehensively corrected the violation; that is the NRC would not consider past performance, duration, multiple occurrences, prior opportunities to identify and correct the violation earlier if the licensee identified and corrected the violation prior to NRC identifying the violation, the NRC scheduling an announced inspection in the area that encompasses the violation, or an event that disclosed the violation. Commenters who favor this approach should address the question of whether this approach would reduce the incentives to identify violations, including responding to opportunities to identify potential violations, or assuring lasting corrective action because the licensee may take the risk that NRC might not identify the violation as a result of the limited, audit nature of the NRC inspection program. How should reporting of a violation be considered? For example, should full mitigation be allowed if a violation was not reported?

(c) Basing sanctions on a combination of approaches (a) and (b) above, similar to the current NRC approach. Commenters who favor this approach should address which factors should be included in establishing sanctions and the weight that might be appropriate for each factor.

6. The Enforcement Policy is intended to provide regulatory messages to improve performance such as encouraging identification of violations, being responsive to information that may suggest the need to take action to determine the existence of a violation, taking prompt, comprehensive and lasting corrective action, and addressing performance problems.

(a) Does the enforcement correspondence that transmits the enforcement actions adequately convey the above messages?

(b) Does the enforcement correspondence that transmits the enforcement actions adequately convey the significance the NRC places on the violations, the areas where improvement in performance are needed, and the reasons for the sanctions?

(c) Is the enforcement correspondence understandable? Should it be simplified? If so, how?

7. Should there be different enforcement policies and procedures (e.g., correspondence, enforcement conferences, inspection documentation, civil penalty assessment factors) for large licensees, such as power reactors and major fuel facilities, and for smaller licensees? If so, how should the policies and procedures differ?

B. Severity Levels of Violations

Violations are normally categorized in terms of five levels of severity to show their relative importance within a particular activity area such as "reactor operations" or "health physics." The level of severity assigned is intended to be based on the violation's actual or potential safety consequence and regulatory significance within the selected activity area. Specific examples of severity levels for particular violations are given in the Enforcement Policy supplements to improve

consistency and enhance the ability to apply the policy.

1. Should the NRC continue to use the existing severity levels to categorize regulatory and safety significance of violations? If not, why not and how should the Enforcement Policy be changed?

2. Is there a benefit to have both a Severity Level IV and V? Should severity levels be used at all if violations are not associated with a civil penalty?

3. Recognizing that not all violations are of equal significance, are there sufficient examples to categorize the range of significance of violations?

(a) Do the existing examples appropriately reflect significance? If not, why not?

(b) If the existing examples are not sufficient, what other examples should be included?

(c) Should the examples be revised to be more general? More specific?

(d) Is sufficient flexibility provided to consider willfulness and other circumstances? What circumstances not now considered should be considered, if any, in establishing a severity level?

C. Enforcement Conferences

The Enforcement Policy provides that when the NRC learns of a potential violation for which escalated enforcement action may be warranted, the NRC normally provides the licensee an opportunity for an enforcement conference prior to taking enforcement action. A conference may also be held for a Severity Level IV violation if increased management attention is warranted. The purpose of the conference is to discuss the potential violations, their significance, the reason for their occurrences including the root causes, and the licensee's corrective actions. It provides NRC management an opportunity to emphasize, directly with senior licensee management, the significance of the violations and the need for effective lasting corrective action. Also, the NRC uses the conference to determine whether there were any aggravating or mitigating circumstances, and to obtain any other information, including whether the licensee questions the findings of the inspection, which may assist in determining the appropriate enforcement action.

Enforcement conferences are not routinely open to the public. (However, a trial program to open about 25 percent of the conferences to the public is currently underway. See footnote 2)

1. Do enforcement conferences serve the purposes stated above? If not, how can they be improved?

2. What are the benefits and weaknesses of conducting enforcement conferences?

3. In deciding whether to hold a conference, should the NRC consider whether the licensee desires to attend a conference?

4. Is the current criteria used to hold a conference appropriate? If not, when should conferences be held?

5. Recognizing that apparent violations may be reconsidered following an enforcement conference, should NRC continue the practice of issuing inspection reports that address the apparent violations prior to an enforcement conference?

6. Enforcement conferences are normally held in regional offices. Should this continue, or should they be held closer to the facility of the licensee?

7. As to open enforcement conferences:

(a) Have open enforcement conferences affected NRC performance during the conference? If so, how?

(b) Have open enforcement conferences impacted the licensee's participation in the conference? If so, how?

(c) Have open conferences impacted the licensees' cost of participating at conferences? If so, how? If more preparation is required, how substantial is that preparation and why should the presence of public attendance impact the licensee's presentation?

(d) Has the public benefited from the ability to observe enforcement conferences?

(e) Should all enforcement conferences be transcribed with the transcript subsequently made public? For those who oppose open conferences, would that be a viable alternative to open enforcement conferences?

(f) The NRC staff in Rockville, Maryland frequently participates in closed enforcement conferences held in the region by telephone.

(i) Is that appropriate for open conferences?

(ii) Should the public be allowed to listen by telephone to open conferences?

(g) Should open enforcement conferences be made a permanent part of the enforcement program?

8. Are there circumstances where a Demand for Information may be an appropriate substitution for an enforcement conference? If so, what circumstances should be considered?

D. Notices of Violations

The policy of the Commission has been to formalize the occurrence of a violation by issuance of a Notice of Violation and by requiring documented corrective action.

1. There are circumstances provided in the Enforcement Policy for not issuing a formal notice of violation to provide incentives for identification and corrective action for violations at Severity Level IV, as well as to save both NRC and licensee resources for violations at Severity Level V. In general where the licensee has identified a non-recurring violation at Severity Level IV and taken appropriate corrective action, the inspection finding is documented in the inspection report and closed out as a "non-cited violation," with no written response required.

(a) Should the circumstances for use of non-cited violations be changed to cover more situations or fewer (including different severity levels)? If so, explain.

(b) Does the use of non-cited violations contribute to providing an incentive for identifying and correcting violations or does it have the same negative impact as a cited violation in a Notice of Violation?

(c) Should non-cited violations be treated any differently from a cited violation when considering compliance history in the deliberations on the appropriate regulatory response to a subsequent violation? If so, explain.

(d) Should NRC continue to use non-cited violations?

(e) If non-cited violations should not be used in the future, how should the NRC disposition findings in an inspection report that provides sufficient detail to demonstrate that a violation occurred? How should NRC track these findings and what should they be called?

2. Is there any purpose to issuing Notices of Violations at Severity Level V? Should all such violations be treated as non-cited violations?

3. Should all Notices of Violations require a written response? If not, what should the documentation requirements be for corrective action? What access rights should be given to the public to review the documentation?

4. The materials program utilizes NRC Form 591, " Safety Inspections," which an inspector may use to document certain violations and after the licensee signs the form stating that corrective action will be taken within 30 days, serves as a Notice of Violation. Form 591 is intended to be issued by the inspector directly to the licensee without further agency review at the conclusion of the inspection.

(a) Should this process be expanded to cover fuel cycle and reactor licensees?

(b) Should this process be expanded to cover other enforcement sanctions?

E. Civil Penalties

A civil penalty is a monetary penalty that may be imposed for certain violations. Civil penalties are intended to emphasize the need for lasting remedial action, and to deter future violations both by the licensed party and by other licensees conducting similar activities.

The base civil penalty amounts have not been changed since the early 1980's. To maintain a constant dollar amount for civil penalties, adjustment for inflation would increase the current amounts by more than 60 percent. For smaller licensees, a civil penalty may be a deterrent because of the financial impact; for power reactor licensees, the current civil penalty amounts are of little financial impact, but may have a deterrent effect through the adverse publicity that attends the issuance of a civil penalty.

1. Should civil penalties continue to be part of the NRC regulatory process? If not, why not? How and when should they be used?

2. Have civil penalties been effective in improving compliance and providing deterrence? If so, why? If not, why not?

3. The Review Team on Reassessment of the NRC's Program for Protecting Allegers Against Retaliation concluded that higher civil penalties are appropriate and recommended a statutory amount of $500,000. The legislative history for section 234 of the Atomic Energy Act does not provide a specific basis for the current statutory amount of $100,000. The recommendation of that Review Team was based on the average cost of a day of replacement power for a power reactor. The recommended increase was intended to provide a more financially relevant penalty and provide for a greater spread of penalty amounts among the severity levels. (See, NUREG 1499 at page II.D–5–6)

(a) Given that significant violations continue to be identified, and that civil penalties are intended to have a punitive aspect, would higher civil penalties provide a greater incentive for compliance for the larger licensees regulated by the Commission?

(b) Should the statutory amount of civil penalties be increased? If so, to what extent? If not, why not?

(c) Since the civil penalty amount in Section 234 of the Atomic Energy Act was last amended in 1980, there has been considerable inflation. Should the base civil penalties be indexed for inflation?

(d) Should the civil penalty amount take into consideration the costs associated with an enforcement action including the cost of the investigation and processing the action?

4. Should the amount of the penalty be normally based solely on the existence of the violation similar to a traffic ticket? If so, why? If not, why not?

(a) If not, are there some violations such as overexposures to workers, releases of radioactive material, exposures to members of the public, failure to use survey instruments by radiographers, etc, where civil penalties should be assessed without regard to adjustment factors? If not, why not?

(b) Does it matter whether a penalty is increased or decreased from the base amount, or is the existence of a penalty the controlling factor?

5. Should the penalty consider contributing factors, such as the root cause of or the licensee's response to the violation? If so, why? If not, why not?

6. The current adjustment factors are designed to encourage good performance (e.g., prompt identification, prompt and comprehensive corrective action, and evidence of past lasting corrective action) and deter poor performance (e.g., lack of identification and prompt or comprehensive corrective action, not being responsive to opportunities to identify violations, and not taking lasting corrective action). The NRC expends considerable effort to adjust civil penalties to provide an appropriate regulatory message.

(a) Should the current civil penalty adjustment factors continue to be used? If not, why not and which factors should be deleted or what factors should be added?

(b) Do the current adjustment factors provide the intended incentives or deterrence? If not, please explain.

7. Comments are requested on the use of the specific factors.

(a) Should there be any mitigation for self-disclosing events where the violation is relatively obvious, i.e., given the event, the licensee really has no choice but to pursue it to determine the cause? If not, why not? If so, why?

(b) Should mitigation be allowed for corrective action, if the individuals responsible for the violations, assuming adequate resources, training, procedures, and supervision, have not been appropriately disciplined? How extensive should corrective action be to permit mitigation?

(c) Since enforcement should be designed to influence performance, should past poor performance be considered and cause penalties to be increased if current performance is good, i.e., the licensee identifies and corrects the particular violation assuming recent performance (e.g., six months) has been good and there has not been a failure to be responsive to opportunities of prior notice? Similarly, should past good performance be considered and cause penalties to be lowered where current performance is not good, i.e. the licensee does not identify and corrects the violations?

(d) The Atomic Energy Act provides that each day a violation continues shall be considered a separate violation for assessing a civil penalty. The longer a violation exists the likelihood of a consequence increases. Should duration be routinely considered if a civil penalty would otherwise be assessed? If not, why not and how should duration be factored into the amount of the penalty?

(e) Should prompt, comprehensive corrective action by the licensee be sufficient to warrant full mitigation of the civil penalty, regardless of the other factors such as prior performance, duration, prior opportunities, and lack of identification or reporting?

(f) Should there be civil penalties if the licensee identifies and promptly and comprehensively corrects a violation? If so, how should factors such as repetitive violations, past poor performance, prior opportunities to have identified the violation earlier, multiple examples and duration be considered?

(g) Reporting is not currently considered as an assessment factor and reporting failures are considered for enforcement separate and apart from the matter not reported. How should reporting issues be considered?

(i) Should there be full mitigation if a licensee identifies a violation associated with a reportable matter, when the report is not properly made?

(ii) Should reporting a violation be considered a separate mitigating factor? If so, should mitigation be allowed where the matter reported was required to be reported since not to do so would be a separate violation subject to a separate sanction?

(iii) Should there be a separate sanction for reporting failures apart from the violation not reported?

(h) In applying the factors of past performance and prior opportunities to identify violations, over what time period should these factors be considered (e.g., events that occurred two years prior to the violation for which the current sanction is being considered)?

(i) Is it appropriate to consider the same facts in determining the existence of a violation, its severity level, and in the application of the assessment factors (e.g., in a corrective action violation escalating a penalty for opportunities to correct a matter earlier and considering the delay as added significance in

establishing the severity level)? If not, why not?

8. The Enforcement Policy provides some flexibility in applying the adjustment factors but it does provide specified percentages to limit the application of the factors.

(a) Should the Enforcement Policy be changed to permit consideration of factors without providing specified percentages that should be used for the assessment? If not, why not?

(b) If so, should there be any outer limit other than the statutory maximum per violation?

(c) The deletion of percentages will permit greater judgement and flexibility to arrive at an appropriate penalty. Will this create a concern for consistency and predictability?

9. Regional Administrators have been delegated the authority to issue civil penalties for certain materials cases without review by the Office of Nuclear Materials, Safety and Safeguards, Office of Enforcement, or the Office of General Counsel.

(a) Should delegation be similarly considered for certain reactor cases? If so, what cases warrant such delegation and why? If delegation is not appropriate, why not?

(b) Are there some violations for which the inspector or section chief should be allowed to issue proposed civil penalties without further agency review? (See question D.4)

10. The Enforcement Policy in Table I.A establishes base civil penalties for different types of licensees. In developing the table it was intended that generally, operations involving greater nuclear inventories and greater potential consequences to the public and licensee employees would receive higher civil penalties and that the amounts, as a secondary factor, would reflect an ability to pay the penalty. Table I.A does not reflect that for a given type of licensee there can be a wide range in sizes, abilities to pay, and potential hazards (e.g., large broad base hospitals in comparison to small rural community hospitals, large research reactors in comparison to very small reactors, or nation wide radiographer firms in comparison to one person radiographer firms).

(a) Should Table I.A reflect different sizes of licensees and different hazards for a given type of licensee? If so, how should this be considered and reflected in the Enforcement Policy?

(b) Are the categories of licensees listed in Table I.A appropriate? If not, what changes should be made and why?

(c) Are the base civil penalties amounts in Table I.A of the Enforcement Policy appropriate for the different types of licensees? If not, what changes should be made and why?

(d) Are the percentages listed in Table I.B appropriate for the different severity levels (e.g., 80 percent of the base civil penalty for a Severity Level II violation)? If not, what changes should be made and why?

F. Orders and Confirmatory Action Letters

An order is a written NRC directive to modify, suspend, or revoke a license, or cease and desist from a practice or activity. A Confirmatory Action Letter is a document that reflects commitments made by a licensee which may in some cases reflect significant obligations. Unlike an order, it does not create legal obligations other than a reporting requirement if an obligation is not met.

1. Should orders be used to a greater or lesser extent than at present?

2. Should Confirmatory Action Letters be used to a greater or lesser extent than at present?

3. Under what circumstances should a Confirmatory Action Letter be used as a substitute for an order?

4. Are licensees actions in response to Confirmatory Action Letters different from orders? Do licensees treat them differently?

G. Exercise of Discretion

The Enforcement Policy in Section VII. A and B provides guidance on when to exercise discretion, and either escalate or mitigate enforcement sanctions, to ensure that the resulting enforcement action appropriately reflects the level of NRC concern, and conveys the appropriate regulatory message to the licensee. [Note, the enforcement review is not addressing section VII.C. of the Enforcement Policy entitled, "Exercise of Discretion for an Operating Reactor" that addresses "Notices of Enforcement Discretion."]

1. Is the guidance provided for exercise of discretion adequate?

2. Should there be additional examples where discretion should be exercised? For example, should facilities that are recognized by the NRC to be poor performers (sometimes referred to as plants on the "watch list" or "problem plant list") continue to be subject to civil penalties during the period of time it takes to improve their performance which normally takes some time to achieve? Should such discretion be exercised even if an average performer with the same violations would receive a civil penalty? Should the response be dependent on whether the plant is shut down or operating? Should the response be dependent on whether the licensee or the NRC identifies the violation?

H. Timeliness of Enforcement Actions

The NRC attempts to issue routine escalated enforcement actions within eight weeks of identification of the potential enforcement issue. An enforcement conference is typically held within four weeks of completion of an inspection.

1. Are these timeliness guidelines for issuance of escalated enforcement actions appropriate?

2. Enforcement conferences are usually scheduled at the convenience of the NRC in the interest of timely enforcement actions. In scheduling enforcement conferences, should NRC schedule them at the mutual convenience of both the NRC and licensee even if it delays the enforcement action, assuming that the delays are not unreasonable?

3. Some enforcement cases take considerably longer than the eight week goal noted above. Has such delay substantially impacted licensees? Is such delay a significant concern? Explain.

4. If the time to process an escalated enforcement action should be reduced, should it be done at the expense of omitting review by the Office of General Counsel, Office of Enforcement, or the appropriate program office?

I. Violations Involving Willfulness and Actions Against Persons for Wrongdoing

The NRC's Enforcement Policy identifies willful violations to be of particular concern, and provides for escalation of the severity level of a violation based on willfulness.

1. Does the Enforcement Policy appropriately reflect the significance of willful violations? If not, how should the Policy be changed to better reflect the significance of willful violations?

2. Is sufficient guidance provided for developing sanctions against licensees for willful violations? If not what additional guidance or criteria would be appropriate?

3. Is sufficient guidance provided for developing consistent sanctions against individuals for wrongdoing? If not, what additional guidance or criteria would be appropriate?

4. NRC focuses its enforcement actions on licensees. Normally the NRC when it issues sanctions to licensees' employees, contractors or other agents, also issues sanctions to licensees. Should the NRC issue enforcement actions to licensees when sanctions are also issued to their employees, contractors or other agents? If not, why

not, and under what circumstances should action not be taken against licensees for the actions of others?

5. Should orders be used more frequently against individuals who violate the rule on deliberate misconduct (e.g., 10 CFR 30.10, 40.10, and 50.5)? Does the potential for the use of such orders increase accountability by employees and contractors? Do employees and contractors appreciate that they may be subject to direct action by the NRC?

6. Should the NRC use civil penalties against individual wrongdoers who violate regulations such as 10 CFR 30.10 and 10 CFR 50.5 in lieu of orders which impact the employees' livelihood?

7. A Letter of Reprimand is used to notify an individual of a violation when a formal sanction is not warranted. Should a Letter of Reprimand be used rather than a more formal action such as a Notice of Violation or an order where the individual has willfully violated a requirement? If so, under what circumstances? For example, should it be used in cases where a relatively low level employee has been fired as a result of the violation and the employee appears to be candid and remorseful.

8. If a criminal sanction is issued against an employee or agent of a licensee who caused the violation, should civil sanctions be issued against the licensee who is licensed by the NRC for the activity?

9. The Enforcement Policy also states that civil penalties are considered for all willful violations. However, to encourage licensees to identify willful violations and to take strong remedial actions to demonstrate the seriousness of such violations to other employees and contractors thereby creating a deterrent effect, discretion may be exercised for certain willful violations at Severity Level IV or V. Is this consistent with the seriousness of willful violations and should this policy be continued? Should it be expanded to other severity levels?

J. Additional Comments

In addition to the above specific issues, commenters are invited to provide any other views on the NRC enforcement program which may assist the NRC in improving the effectiveness of NRC enforcement efforts.

Dated at Rockville, Maryland, this 16th day of August 1994.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

[FR Doc. 94–20618 Filed 8–22–94; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–NM–27–AD]

Airworthiness Directives; Boeing Model 747–100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Boeing Model 747–100 series airplanes, that currently requires repetitive inspections to detect cracking of the wing front spar web above engine numbers 2 and 3, and repair, if necessary. This action would require repetitive inspections to detect cracks in the web and cracked or broken fasteners in an area beyond that specified in the existing AD. This action also would provide an optional terminating action for the repetitive inspections. This proposal is prompted by reports of broken fasteners and cracking of the web common to the upper and lower chords in an area outside the inspection zone specified in the existing AD. The actions specified by the proposed AD are intended to prevent fuel leakage onto an engine and a resultant fire due to cracking or broken fasteners in the wing front spar.

DATES: Comments must be received by October 17, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–27–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2776; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 94–NM–27–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–27–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On March 10, 1992, the FAA issued AD 92–07–11, amendment 39–8207 (57 FR 10415, March 26, 1992), applicable to certain Boeing Model 747–100 series airplanes, to require inspections to detect cracking of the wing front spar web above engine numbers 2 and 3, and repair, if necessary. That action was prompted by a report of an 18-inch crack in the front spar web at the attach fitting of the number 3 engine. The requirements of that AD are intended to prevent fuel leakage onto an engine and a resultant fire.

Since the issuance of that AD, the FAA has received reports of broken fasteners and cracking in the fastener holes of the web common to the upper and lower chords in areas outside the inspection zone specified in AD 92–07–11. The airplanes on which these cracks

and broken fasteners were found had accumulated between 13,700 and 22,000 flight cycles. Based on these findings, the FAA has determined that inspections to detect cracks and broken fasteners in an area beyond that specified in AD 92–07–11 are necessary.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994, which describes procedures for repetitive detailed visual inspections of the chords, stiffeners, and rib posts between the fastener heads and ultrasonic inspections to detect cracks of the wing front spar web between front spar stations (FSS) 570 and 684. The alert service bulletin also describes procedures for repetitive ultrasonic inspections of the fasteners in the web-to-chords, web-to-stiffeners, and web-to-rib posts to detect cracked or broken fasteners between FSS 570 and 684. For those airplanes on which cracks or broken fasteners are found, the alert service bulletin also describes procedures for oversizing fastener holes, performing an eddy current inspection to detect cracking of the fastener holes, and replacing cracked fasteners with oversized fasteners. The alert service bulletin also describes procedures for replacement of certain fasteners with oversized fasteners, which, if accomplished, would eliminate the need for the repetitive inspections.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 92–07–11 to require repetitive detailed visual and ultrasonic inspections to detect cracks in an area beyond that specified in the existing AD; and repetitive ultrasonic inspections of the fasteners in the web-to-chords, web-to-stiffeners, and web-to-rib posts to detect cracked or broken fasteners between FSS 570 and 684. If any cracked or broken fastener is found, this proposed AD would require oversizing the fastener holes, performing an eddy current inspection to detect cracking of the fastener holes, and replacing cracked fasteners with oversized fasteners. This proposed AD also would provide an optional terminating action for the repetitive inspections. The actions would be required to be accomplished in accordance with the alert service bulletin described previously.

There are approximately 190 Model 747–100 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 95 airplanes of U.S. registry would be affected by this proposed AD.

The inspections that were required previously by AD 92–07–11, and retained in this AD, take approximately 16 work hours per airplane to accomplish, at an average labor rate of $55 per work hour. Based on these figures, the total cost impact of that inspection requirement on U.S. operators is estimated to be $83,600, or $880 per airplane, per inspection cycle.

The FAA estimates that it would take approximately 54 work hours per airplane to accomplish the proposed inspections of the expanded area specified in this AD, and that the average labor rate is $55 per work hour. Based on these figures, the future total cost impact of the inspection requirement of the expanded zone on U.S. operators is estimated to be $282,150, or $2,970 per airplane.

Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $365,750, or $3,850 per airplane.

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator elect to accomplish the optional terminating action (fastener replacement between FSS 570 and FSS 684) that would be provided by this AD action, it would take approximately 306 work hours to accomplish it, at an average labor rate of $55 per work hour. The cost of required parts would be provided by the manufacturer at no cost to operators. Based on these figures, the total cost impact of the optional terminating action would be $16,830 per airplane.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8207 (57 FR 10415, March 26, 1992), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 94–NM–27–AD. Supersedes AD 92–07–11, Amendment 39–8207.

Applicability: Model 747–100 series airplanes; as listed in Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel leakage onto an engine and a resultant fire, accomplish the following:

Restatement of Actions Required by AD 92–07–11, Amendment 39–8207:

(a) For airplanes listed in Boeing Alert Service Bulletin 747–57A2266, dated June 6, 1991, on which the optional terminating action (fastener replacement) specified in the original issue, dated June 6, 1991; Revision 1, dated May 21, 1992; or Revision 2, dated June 10, 1993; of the alert service bulletin has not been accomplished: Perform a visual inspection and an ultrasonic inspection to detect cracks of the wing front spar web between front spar station (FSS) 636 and FSS 675 in accordance with Boeing Alert Service Bulletin 747–57A2266, dated June 6, 1991; Revision 1, dated May 21, 1992; Revision 2, dated June 10, 1993; or Revision 3, dated March 31, 1994; at the time specified in paragraph (a)(1), (a)(2), or (a)(3) of this AD, as applicable. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles until the inspections required by paragraph (b) of this AD are accomplished.

(1) For airplanes that have accumulated more than 20,000 total flight cycles as of May 4, 1992 (the effective date of AD 92–07–11, amendment 39–8207): Inspect within 6 months after May 4, 1992.

(2) For airplanes that have accumulated between 15,000 and 20,000 total flight cycles as of May 4, 1992: Inspect within 15 months after May 4, 1992.

(3) For airplanes that have accumulated less than 15,000 total flight cycles as of May 4, 1992: Inspect within 15 months after accumulating 15,000 total flight cycles.

New Actions Required by This AD:

(b) For airplanes on which the terminating action (fastener replacement) specified in Boeing Alert Service Bulletin 747–57A2266, dated June 6, 1991; Revision 1, dated May 21, 1992; or Revision 2, dated June 10, 1993; has not been accomplished: Prior to the accumulation of 13,000 total flight cycles, or within 6 months after the effective date of this AD, or within 1,000 flight cycles after the immediately preceding inspection accomplished in accordance with paragraph (a) of this AD, whichever occurs later, accomplish the inspections specified in paragraphs (b)(1), (b)(2), and (b)(3) of this AD in accordance with Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles. Accomplishment of these inspections terminates the inspections required by paragraph (a) of this AD. After the effective date of this AD, the inspections required by this paragraph shall be accomplished only in accordance with Revision 3 of the alert service bulletin.

(1) Perform a detailed visual inspection of the chords, stiffeners, and rib posts between the fastener heads; and

(2) Perform an ultrasonic inspection of the web under the upper and lower chord footprints to detect cracking of the wing front spar web between FSS 570 and FSS 684; and

(3) Perform an ultrasonic inspection of the fasteners in the web-to-chords, web-to-stiffeners, and web-to-rib posts to detect cracked or broken fasteners between FSS 570 and FSS 684.

(c) For airplanes on which the terminating action (fastener replacement) specified in Boeing Alert Service Bulletin 747–57A2266, dated June 6, 1991; Revision 1, dated May 21, 1992; or Revision 2, dated June 10, 1993; has been accomplished: Within 18 months after accomplishing the terminating action specified in the original issue, Revision 1, or Revision 2 of the alert service bulletin, or within 9 months after the effective date of this AD, whichever occurs later, accomplish the inspections specified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD in accordance with Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles. After the effective date of this AD, the inspections required by this paragraph shall be accomplished only in accordance with Revision 3 of the alert service bulletin.

(1) Perform a detailed visual inspection of the chords, stiffeners, and rib posts between the fastener heads; and

(2) Perform an ultrasonic inspection of the web under the upper and lower chord footprints to detect cracking of the wing front spar web between FSS 570 and FSS 636 and between FSS 675 and FSS 684; and

(3) Perform an ultrasonic inspection of the fasteners in the web-to-chords, web-to-stiffeners, and web-to-rib posts to detect cracked or broken fasteners between FSS 570 and FSS 636 and between FSS 675 and 684.

(d) If any crack in the web or any cracked or broken fastener is found during any inspection required by this AD, prior to further flight, oversize the fastener hole, perform an eddy current inspection to detect cracks in the fastener hole, and replace the fastener with an oversized fastener, in accordance with Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994. Thereafter, continue to inspect the remaining fasteners in accordance with paragraph (b) or (c) of this AD, as applicable, until the terminating action specified in paragraph (e) of this AD is accomplished. If any crack is found that cannot be removed by oversizing the fastener hole, prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

(e) Replacement of the fasteners in the web-to-chords and of the fasteners in the web-to-stiffeners and web-to-rib posts, as specified in Boeing Alert Service Bulletin 747–57A2266, Revision 3, dated March 31, 1994, with oversized fasteners on each wing spar in accordance with the alert service bulletin constitutes terminating action for the repetitive inspections required by paragraph (b) and (c) of this AD.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 17, 1994.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–20593 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 71

[Airspace Docket No. 93–ASW–57]

Proposed Modification of Class D and Revocation of Class E Airspace: Altus, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to modify the Class D airspace at Altus, OK to delete the 4-mile circle that surrounds Altus Municipal Airport. This notice also proposes to revoke the Class E extension to the Altus, OK Class D airspace extending upward from the surface within 2 miles each side of the 360° bearing from the Altus Municipal Airport and extending from the 4-mile radius of Altus Municipal Airport to 6.5 miles north of the airport. These portions of the Class D and Class E airspace are no longer required for instrument flight rule (IFR) operations at Altus Air Force Base (AFB), OK. The intended effect of this proposal is to remove that portion of Class D airspace outside the 5-mile circle surrounding Altus AFB that encompasses Altus Municipal Airport and to revoke the Class E extension to the Altus, OK Class D airspace.

DATES: Comments must be received on or before October 4, 1994.

ADDRESSES: Send comments on the proposal in triplicate to Manager, System Management Branch, Air Traffic Division, Southwest Region, Docket No. 93–ASW–57, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530.

The official docket may be examined in the Office of the Assistant Chief Counsel, Southwest Region, Federal Aviation Administration, 2601 Meacham Boulevard, Room 663, Fort Worth, TX, between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the System Management Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, 2601 Meacham Boulevard, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Alvin DeVane, System Management Branch, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530; telephone: 817–222–5595.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the

airspace docket and be submitted in triplicate to the address listed under the caption **ADDRESSES.** Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit, with those comments, a self-addressed, stamped, postcard containing the following statement: "Comments to Airspace Docket No. 93–ASW–57." The postcard will be date and time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the office of the Assistant Chief Counsel, at 2601 Meacham Boulevard, Forth Worth, TX, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Manager, System Management Branch, Department of Transportation, Federal Aviation Administration, Forth Worth, TX 76193–0530. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A that describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify the Class D airspace at Altus, OK and to revoke the Class E extension to the Altus, OK Class D airspace. This modification is being proposed due to requests by aircraft operators of Altus Municipal Airport and Altus AFB. The FAA has reviewed these requests and have determined that control of portions of the Class D and the Class E extension is no longer needed. The intended effect of this proposal is to modify the Class D airspace to maintain IRF operations and two-way radio communications for Altus AFB but remove that portion of the current Class D airspace and the Class E extension to the Class D airspace that is no longer required.

The coordinates for this airspace docket are based on North American Datum 83. Class D airspace designations are published in Paragraph 5000 and Class E airspace designated as an extension to a Class D surface area are published in Paragraph 6004 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class D and Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993 is amended as follows:

Paragraph 5000 General

* * * * *

ASW OK D Altus, OK. [Revised]

Altus AFB, OK.
(lat. 34°39'50" N., long. 99°16'26" W.)
Altus AFB ILS Localizer
(lat. 34°38'31" N., long. 99°16'24" W.)

That airspace extending upward from the surface to and including 3,900 feet MSL within a 5-mile radius of Altus AFB and within 2 miles each side of the Altus AFB ILS Localizer south course extending from the 5-mile radius to 6.6 miles south of Altus AFB and within 2 miles each side of the Altus AFB ILS Localizer north course extending from the 5.0-mile radius to 7.6 miles north of Altus AFB.

* * * * *

Paragraph 6004 Class E airspace areas designated as an extension to a Class D surface area

* * * * *

ASW OK E4 Altus, OK. [Remove]

* * * * *

Issued in Fort Worth, TX on July 20, 1994.

Helen Fabian Parke,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 94–20669 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 94–ASW–03]

Proposed Revision of Class E Airspace

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to revise the Class E airspace at Oakdale, Louisiana. Restricted Area R–3806, has been relocated. The Class E Airspace is being revised to reflect the relocation of that Restricted Area, R–3806. The intended effect of this proposal is to revise the Class E airspace to provide adequate controlled airspace extending upward from 700 feet above ground level for aircraft executing the Nondirectional Radio Beacon (NDB) standard instrument approach procedure (SIAP) at Allen Parish Airport, Oakdale, Louisiana.

DATES: Comments must be received on or before October 4, 1994.

ADDRESSES: Send comments on the proposal in triplicate to Manager, System Management Branch, Air Traffic Division, Southwest Region, Docket No. 94–ASW–03, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530.

The official docket may be examined in the office of the Assistant Chief Counsel, Southwest Region, Federal Aviation Administration, 2601 Meacham Boulevard, Fort Worth, TX, between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the System Management Branch, Air Traffic Division, Southwest Region, Federal Aviation

Administration, 2601 Meacham Boulevard, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT:

Gregory L. Juro, System Management Branch, Department of Transportation, Federal Aviation Administration, Forth Worth, TX 76193–0530; telephone: (817) 624–5591.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed under the caption "Addresses." Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit, with those comments, a self-addressed, stamped, postcard containing the following statement: "Comments to Airspace Docket No. 94–ASW–03." The postcard will be date and time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the office of the Assistant Chief Counsel, 2601 Meacham Boulevard, Fort Worth, TX, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, Department of Transportation, Fort Worth, TX 76193–0530. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A that describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace at Allen Parish Airport, Oakdale, Louisiana. Restricted Area R–3806, near Allen Parish Airport, has been relocated. Controlled airspace extending upward from 700 feet above ground level (AGL) is needed for instrument flight rule (IFR) operations at the airport. The intended effect of this proposal is to provide adequate class E airspace for aircraft executing the NDB SIAP at Allen Parish Airport.

The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas designated for airspace areas extending upward from 700 feet or more above ground level are published in Paragraph 6005 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The class E airspace designation listed in this document would be published subsequently in the order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW LA E5 Oakdale, LA [Revised:]

Allen Parish Airport
(latitude 30°45'01" N., longitude 92°41'18" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Allen Parish Airport.

* * * * *

Issued in Fort Worth, TX on July 20, 1994.

Helen Fabian Parke,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 94–20665 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 94–ASO–19]

Proposed Establishment of Class E Airspace; Georgetown, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Georgetown, Kentucky. A Standard Instrument Approach Procedure (SIAP) to the Georgetown Scott County-Marshall Field Airport has been developed and controlled airspace from 700 feet to 1200 feet above ground level (AGL) is needed for IFR operations at the airport. The intended effect of this proposal is to provide adequate Class E airspace for IFR operations within controlled airspace. If approved, the operating status of the airport would change from VFR to include IFR operations, concurrent with publication of the SIAP.

DATES: Comments must be received on or before: October 10, 1994.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 94–ASO–19 Manager, System Management Branch, ASO–530, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief

Counsel for Southern Region, Room 530, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5200.

FOR FURTHER INFORMATION CONTACT: Ralph C. Bixby, Airspace Section, System Management Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5589.

SUPPLEMENTARY INFORMATION;

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 94–ASO–19." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 530, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM'S

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, System Management Branch (ASO–530), Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at Georgetown, Kentucky. A SIAP based on the Lexington Very High Frequency Omnidirectional Range (VOR) has been established to serve the Georgetown Scott County-Marshall Field Airport. Controlled airspace extending from 700 feet 59 1200 feet AGL is needed for IFR operations at the airport. The intended effect of this proposal is to provide adequate Class E airspace for IFR operators executing the VOR/DME Runway 03 SIAP at the airport. The coordinates for this airspace docket are based on North American Datum 83. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9A dated June 17, 1993 and effective September 16, 1993, which is incorporated by reference in CFR 71.1 effective September 16, 1993. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71 [AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993 and effective September 16, 1993, is amended as follows:

Para 6005 Class E airspace areas extending upward from 700 feet above the surface of the earth.

* * * * *

ASO KY E5 Georgetown, KY [New]

Georgetown Scott County-Marshall Field Airport, KY
(Lat. 38°14'10" N Long. 84°26'01" W)
Lexington, Blue Grass Airport, KY
(Lat. 38°02'13" N Long. 84°36'19" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Georgetown-Scott County Airport, Georgetown, KY; and that airspace extending upward from 700 feet above the surface within 2-miles either side of a bearing 185 degrees from the airport extending from 6.5-mile radius to 8.5-miles southwest of the airport, excluding that airspace designated as the Lexington, KY, 700-foot Class E airspace.

* * * * *

Issued in College Park, Georgia, on July 29, 1994.

Walter E. Denley,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 94–20664 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 94–ANM–43]

Proposed Amendment of Class D Airspace; Klamath Falls, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Klamath Falls, Oregon, Class D airspace from full-time to part-time operations due to a recent reduction in military activity at the Klamath Falls International Airport. The rule would provide a statement regarding part-time operations in the Class D airspace description. Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the term "airport traffic area" and "control zone" with operating control towers, replacing

them with the designation "Class D airspace."

DATES: Comments must be received on or before September 30, 1994.

ADDRESSES: Send comments on the proposal to: Manager, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–43, 1601 Lind Avenue S.W., Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the same address.

FOR FURTHER INFORMATION CONTACT: Ted Melland, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–43, 1601 Lind Avenue S.W., Renton, Washington, 98055–4056; telephone number: (206) 227–2536.

SUPPLEMENTARY INFORMATION:

Comments Invited

Aeronautical activity at Klamath Falls International Airport, Oregon, was significantly comprised of military operations. On June 30, 1994, the military alert squadron terminated operations at the airport, thereby nullifying the need for staffing the control tower during the midnight shift.

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 94–ANM–43." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Airspace reclassification, in effect as of September 16, 1993, has discontinued use of the terms "airport traffic area" and "control zone" with operating control towers, and replaced them with the designation "Class D airspace." The coordinates in this NPRM are in North American Datum 83.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, ANM–530, 1601 Lind Avenue S.W., Renton, Washington 98055–4056. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class D airspace at Klamath Falls, Oregon, to provide information regarding modified (reduced) hours of operation at the Air Traffic Control Tower (ATCT). Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the terms "control zone and airport traffic area," and certain airspace areas extending upward from surface of the earth are now Class D airspace areas. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class D airspace areas extending upward from the surface of the earth are published in Paragraph 5000 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class D airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 5000 General

* * * * *

ANM OR D Klamath Falls, OR [Revised]

Klamath Falls International Airport, OR
(lat. 42°09'23" N, long. 121°44'00" W)

That airspace extending upward from the surface to and including 6,600 feet MSL within a 5.4-mile radius of the Klamath Falls International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice of Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on July 25, 1994.

Charles Davis,

Acting Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 94–20663 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 94–ANM–42]

Proposed Amendment to Class E Airspace; Sheridan, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Sheridan, Wyoming, Class E airspace. This action would amend the Sheridan, Wyoming, Class E airspace from full-time back to part-time. This amendment would bring publications up-to-date giving continuous information to the aviation public.

DATES: Comments must be received on or before September 30, 1994.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–42, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: James Riley, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–42, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone number: (206) 227–2537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 94–ANM–42." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, ANM–530, 1601 Lind Avenue SW., Renton, Washington 98055–4056. Communications must identify the notice number of this NPRM.

Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Sheridan, Wyoming. This proposal would amend the Class E airspace from full-time to part-time. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace is published in Paragraph 6002 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport

* * * * *

ANM WY E Sheridan, WY [Revised]

Sheridan County Airport, WY
(lat. 44°46'26" N, long. 106°58'37" W)
Sheridan VORTAC
(lat. 44°50'32" N, long. 107°03'40" W)

Within a 4.4-mile radius of the Sheridan County Airport, and within 3.5 miles each side of the Sheridan VORTAC 312° and 327° radials extending from the 4.4-mile radius to 10.1 miles northwest of the VORTAC, and within 3.5 miles each side of the Sheridan VORTAC 140° radial extending from the 4.4-mile radius to 21.4 miles southeast of the VORTAC. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on July 26, 1994.

Charles Davis,

Acting Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 94–20673 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 94–ANM–33]

Amendment of Class D Airspace; Coeur d'Alene, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Idaho Falls, Idaho, Class D airspace from full-time to part-time operations. Recent staffing reductions, and reduced aeronautical activity, have required adjustment in the operational schedule at the Idaho Falls Airport Traffic Control Tower (ATCT). The rule would provide a statement regarding part-time operations in the Class D airspace description. Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the term "airport traffic area" and "control zone" with operating control towers, replacing them with the designation "Class D airspace."

DATES: Comments must be received on or before September 30, 1994.

ADDRESSES: Send comments on the proposal to: Manager, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–33, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the same address.

FOR FURTHER INFORMATION CONTACT: Ted Melland, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 94–ANM–33, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone number: (206)227–2536.

SUPPLEMENTARY INFORMATION:

Comments Invited

Aeronautical activity at Fanning Field, Idaho Falls, Idaho has decreased, particularly during the midnight to daytime (midwatch) schedule. There has also been a staffing reduction due to normal attrition without staffing replacements. The combined effect of these occurrences necessitate placing the ATCT operation on a part-time basis.

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments of this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 94–ANM–33." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration System Management Branch, ANM–530, 1601 Lind Avenue SW., Renton, Washington 98055–4056. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class D airspace at Idaho Falls, Idaho, to provide information regarding modified (reduced) hours of operation at the ATCT. Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the terms "control zone and airport traffic area," and certain airspace areas extending upward from the surface of the earth are now Class D airspace areas. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class D airspace areas extending upward from the surface of the earth are published in Paragraph 5000 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class D airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 5000 General

* * * * *

ANM ID D Idaho Falls, ID [Revised]

Idaho Falls, Fanning Field, ID
(lat. 43°30'59" N, long. 112°04'05" W)

That airspace extending upward from the surface to and including 7,200 feet MSL within a 5.4-mile radius of Fanning Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on July 26, 1994.

Charles Davis,

Acting Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 94–20674 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

Extension of Port Limits of Hilo and Kahului, HI

AGENCY: U. S. Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations pertaining to the field organization of Customs by extending the geographical limits of the ports of entry of Hilo and Kahului, Hawaii. The proposed change is being made as part of Customs continuing program to obtain more efficient use of its personnel, facilities, and resources and to provide better service to carriers, importers, and the general public.

DATES: Comments must be received on or before October 24, 1994.

ADDRESSES: Written comments (preferably in triplicate) may be submitted to the Regulations Branch, Office of Regulations and Rulings, U. S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, 1099 14th Street NW., Suite 4000, Washington, D.C., on regular business days between the hours of 9 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Brad Lund, Office of Inspection and Control, 202–927–0192.

SUPPLEMENTARY INFORMATION:

Background

As part of a continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and the general public, Customs proposes to amend § 101.3, Customs Regulations (19 CFR 101.3), by extending the geographical limits of the ports of entry of Hilo and Kahului, Hawaii.

In the list of Customs regions, districts, and ports of entry set forth in § 101.3(b), Customs Regulations, Hilo and Kahului are listed as ports of entry in the Honolulu, Hawaii, Customs District within the Pacific Region.

Current Port Limits of Hilo and Hawaii

The current Customs district 32, Honolulu, includes four ports of entry, including Hilo on the island of Hawaii and Kahului on the island of Maui. The port limits of Hilo and Kahului were defined in a Bureau Letter issued by Customs on December 27, 1948.

The current port limits of Hilo include only a part of the district of South Hilo. The exact port limits of Hilo are as follows:

That part of the district of South Hilo, County of Hawaii, which is bounded on the south by the district of Puna; Bounded on the west by the districts of Kau and North Hilo; on the north by the Ahupuaa of Paukaa in the district of South Hilo; and on the east by the breakwater, and the sea from the west end of the breakwater to the shore line at the south boundary of the Ahupuaa of Paukaa.

The port limits are also said to conform to the city limits of Hilo as found in the Revised Laws of Hawaii (1945), Section 6351.

The current port of Kahului includes the seaport area of Kahului only. The Bureau Letter of December 27, 1948, describes the limits of the Port of Kahului as follows:

Beginning at the eastern end of the west breakwater, proceeding along the north side of said breakwater in a westerly direction to the west side of Kahului Beach Road, thence along the west side of Kahului Beach Road in a generally southeasterly direction to its intersection with Main Street, and thence in a westerly direction along Main Street to its intersection with Pine Avenue, thence southerly along Pine Avenue to its intersection with Sixth Street, thence easterly along Sixth Street to its intersection with Puunene Avenue, thence in a straight line to the southeast (SP) corner of the original Kahului Townsite boundary, thence along said boundary in a northerly direction to the low water line of the shore line, thence along the shore line to the base of the east breakwater, thence along the north side of said breakwater to its end, thence across the entrance of the harbor in a straight line to the point of beginning.

The description given above is out of date in that it includes two streets, Pine Avenue and Sixth Street, which no longer exist.

Proposed Expansion of Ports

On the island of Hawaii, Customs currently provides service twice each week to locations on the south (Kona) coast of the island of Hawaii. Barges discharge cargo at Kawalhae. Airplanes arrive at Keahole Airport. (The State of Hawaii had requested that Customs establish an office at Keahole Airport.) Private vessels and commercial fishing vessels occasionally must be boarded at Honokahau. Cruise vessels are processed at Kailua-Kona. All of this activity takes place outside the port limits of Hilo and requires at least a two hour drive from Hilo. In order to include all potential Customs work sites within the port, the District Director of Honolulu suggests that the port limits of Hilo be expanded to include the entire island of Hawaii. Customs personnel would then be stationed at Keahole and would provide necessary Customs service on the Kona Coast of Hawaii.

The current boundaries of the port of Kahului on the island of Maui are also too restrictive in that Kahului Airport is not within port limits. Customs also clears cargo at many locations on Maui, and it processes cruise vessels in Lahaina. The District Director of Honolulu wishes to include all of these work sites within the port by extending the port limits of Kahului to the entire island of Maui. An office would be established at Lahaina.

Expansion of the port limits for these two islands would improve service to the public and make better use of staffing resources.

Proposed Port Limits

The proposed extended limits of the port of Hilo are the entire island of Hawaii. The proposed extended limits of the port of Kahului are the entire island of Maui.

If these proposed extensions of the ports of entry of Hilo and Kahului are adopted, the list of Customs regions, districts and ports of entry in 19 CFR 101.3(b) will be amended accordingly.

Comments

Prior to adoption of this proposal, consideration will be given to written comments timely submitted to Customs. Submitted comments will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and section 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m., at the Regulations Branch, Office of Regulations and Rulings, 1099 14th Street, NW., Suite 4000, Washington, D.C.

Authority

This change is proposed under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66, and 1624.

Regulatory Flexibility Act and Executive Order 12866

Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Thus, although this document is being issued with notice for public comment, because it relates to agency management and organization, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Agency organization matters such as this proposed port extension are exempt from consideration under Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson. Regulations Branch. However, personnel from other offices participated in its development.

Approved: August 10, 1994

George J. Weise,

Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 94–20690 Filed 8–22–94; 8:45 am]

BILLING CODE 4820–20–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

Roof-Bolting-Machine Study and Evaluation Report—Comment Period

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice of availability; comment period.

SUMMARY: The Mine Safety and Health Administration (MSHA) is announcing the availability of a report dealing with safety hazards associated with roof bolting machines. The report identifies safety problems and suggests solutions. The Agency solicits public comment on issues addressed in the report. The report, along with comments received, will be considered by the Agency in identifying subjects for possible future rulemaking.

DATES: Written comments must be submitted on or before September 16, 1994.

ADDRESSES: The report may be obtained from the Business Office of the National Mine Health and Safety Academy, P.O. Box 1166, Beckley, West Virginia, 25802–1166. Phone: (304) 256–3206. Send written comments to "MSHA—Roof Bolter Safety," Division of Safety, Room 807, 4015 Wilson Boulevard, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Administrator, Coal Mine Safety and Health, MSHA, (703)235–9423.

SUPPLEMENTARY INFORMATION: Sixteen miners died between January 1984 and April 1994 from machinery accidents involving roof bolting machines. The Mine Safety and Health Administration formed a committee on April 4, 1994, to evaluate roof-bolting machines and to identify problems with machine design and use that may be contributing to or causing accidents, and to offer solutions to those problems. The committee completed its report on July 8, 1994. The report analyzes machinery accidents involving roof-bolting machine design and use in underground mines. Solutions are offered in the report for some of the problems identified.

The Agency is especially interested in comments addressing solutions to the identified problems. MSHA believes that the report provides a unique opportunity for the mining industry to work together with MSHA to prevent future accidents involving roof bolting machines. Public comments would greatly assist the Agency in determining how best to take action toward improving the safety of miners working with roof bolting machines.

Dated: August 12, 1994.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 94–20579 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–43–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5055–2; Proposed Rule No. 17]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA" or "the Act"), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan ("NCP") include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List ("NPL") constitutes this list.

The Environmental Protection Agency ("EPA") proposes to add new sites to the NPL. This 17th proposed revision to the NPL includes 6 sites in the General Superfund Section and 4 in the Federal Facilities Section. The identification of a site for the NPL is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This action does not affect the 1,232 sites currently listed on the NPL (1,082 in the General Superfund Section and 150 in the Federal Facilities Section). However, it does increase the number of proposed sites to 64 (54 in the General Superfund Section and 10 in the Federal Facilities Section). Final and proposed sites now total 1,296.

DATES: Comments must be submitted on or before October 24, 1994.

ADDRESSES: Mail original and three copies of comments (no facsimiles or tapes) to Docket Coordinator, Headquarters; U.S. EPA CERCLA Docket Office; (Mail Code 5201); Waterside Mall; 401 M Street, SW; Washington, DC 20460; 202/260–3046. For additional Docket addresses and further details on their contents, see Section I of the "Supplementary Information" portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Terry Keidan, Hazardous Site Evaluation Division, Office of Emergency and Remedial Response (Mail Code 5204G), U.S. Environmental Protection Agency, 401 M Street, SW Washington, DC, 20460, or the Superfund Hotline, Phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

I. Introduction

Background

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 ("CERCLA" or

"the Act") in response to the dangers of uncontrolled hazardous waste sites. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act ("SARA"), Public Law No. 99–499, 100 Stat. 1613 et seq. To implement CERCLA, the Environmental Protection Agency ("EPA" or "the Agency") promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan ("NCP"), 40 CFR Part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets forth the guidelines and procedures needed to respond under CERCLA to releases and threatened releases of hazardous substances, pollutants, or contaminants. EPA has revised the NCP on several occasions, most recently on July 14, 1994 (59 FR 35852).

Section 105(a)(8)(A) of CERCLA requires that the NCP include "criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action." As defined in CERCLA section 101(24), remedial action tends to be long-term in nature and involves response actions that are consistent with a permanent remedy for a release.

Mechanisms for determining priorities for possible remedial actions financed by the Trust Fund established under CERCLA (commonly referred to as the "Superfund") and financed by other persons are included in the NCP at 40 CFR 300.425(c) (55 FR 8845, March 8, 1990). Under 40 CFR 300.425(c)(1), a site may be included on the NPL if it scores sufficiently high on the Hazard Ranking System ("HRS"), which is Appendix A of 40 CFR Part 300. On December 14, 1990 (55 FR 51532), EPA promulgated revisions to the HRS partly in response to CERCLA section 105(c), added by SARA. The revised HRS evaluates four pathways: ground water, surface water, soil exposure, and air. The HRS serves as a screening device to evaluate the relative potential of uncontrolled hazardous substances, pollutants, and contaminants to pose a threat to human health or the environment. Those sites that score 28.50 or greater on the HRS are eligible for the NPL.

Under a second mechanism for adding sites to the NPL, each State may designate a single site as its top priority, regardless of the HRS score. This mechanism, provided by the NCP at 40 CFR 300.425(c)(2), requires that, to the extent practicable, the NPL include within the 100 highest priorities, one facility designated by each State representing the greatest danger to public health, welfare, or the environment among known facilities in the State.

The third mechanism for listing, included in the NCP at 40 CFR 300.425(c)(3), allows certain sites to be listed whether or not they score above 28.50, if all of the following conditions are met:

- The Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends dissociation of individuals from the release.
- EPA determines that the release poses a significant threat to public health.
- EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

Based on these criteria, and pursuant to section 105(a)(8)(B) of CERCLA, as amended by SARA, EPA promulgates a list of national priorities among the known or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. That list, which is Appendix B of 40 CFR Part 300, is the National Priorities List ("NPL"). CERCLA section 105(a)(8)(B) defines the NPL as a list of "releases" and as a list of the highest priority "facilities." The discussion below may refer to the "releases or threatened releases" that are included on the NPL interchangeably as "releases," "facilities," or "sites." CERCLA section 105(a)(8)(B) also requires that the NPL be revised at least annually. A site may undergo CERCLA-financed remedial action only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.425(b)(1).

EPA promulgated an original NPL of 406 sites on September 8, 1983 (48 FR 40658). The NPL has been expanded since then, most recently on May 31, 1994 (59 FR 27989).

The NPL includes two sections, one of sites being evaluated and cleaned up by EPA (the "General Superfund Section"), and one of sites being addressed by other Federal agencies (the "Federal Facilities Section"). Under Executive Order 12580 and CERCLA section 120, each Federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody, or control, although EPA is responsible for preparing an HRS score and determining if the facility is placed on the NPL. EPA is not the lead agency at these sites, and its role at such sites is accordingly less extensive than at other sites. The Federal Facilities Section includes those facilities at which EPA is not the lead agency.

Deletions/Cleanups

EPA may delete sites from the NPL where no further response is appropriate under Superfund, as explained in the NCP at 40 CFR 300.425(e) (55 FR 8845, March 8, 1990). To date, the Agency has deleted 59 sites from the General Superfund Section of the NPL.

EPA also has developed an NPL construction completion list ("CCL") to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities (58 FR 12142, March 2, 1993). Sites qualify for the CCL when: (1) any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved; (2) EPA has determined that the response action should be limited to measures that do not involve construction (e.g., institutional controls); or (3) the site qualifies for deletion from the NPL. Inclusion of a site on the CCL has no legal significance.

In addition to the 58 sites that have been deleted from the NPL because they have been cleaned up (the Waste Research and Reclamation site was deleted based on deferral to another program and is not considered cleaned up), an additional 180 sites are also in the NPL CCL, all but one from the General Superfund Section. Thus, as of August 12, 1994, the CCL consists of 244 sites.

Cleanups at sites on the NPL do not reflect the total picture of Superfund accomplishments. As of May 30, 1994, EPA had conducted 627 removal actions at NPL sites, and 2,139 removal actions at non-NPL sites. Information on removals is available from the Superfund hotline.

Pursuant to the NCP at 40 CFR 300.425(c), this document proposes to add 10 sites to the NPL. The General Superfund Section includes 1,082 sites, and the Federal Facilities Section includes 150 sites, for a total of 1,232 sites on the NPL. Final and proposed sites now total 1,296.

Public Comment Period

The documents that form the basis for EPA's evaluation and scoring of sites in this rule are contained in dockets located both at EPA Headquarters and in the appropriate Regional offices. The dockets are available for viewing, by appointment only, after the appearance of this rule. The hours of operation for the Headquarters docket are from 9:00 a.m. to 4:00 p.m., Monday through

Friday excluding Federal holidays. Please contact individual Regional dockets for hours.

Docket Coordinator, Headquarters, U.S. EPA CERCLA Docket Office, (Mail Code 5201), Waterside Mall, 401 M Street SW, Washington, DC 20460, 202/260–3046

Ellen Culhane, Region 1, U.S. EPA Waste Management Records Center, HES-CAN 6, J.F. Kennedy Federal Building, Boston, MA 02203–2211, 617/573–5729

Walter Schoepf, Region 2, U.S. EPA, 26 Federal Plaza, New York, NY 10278, 212/264–0221

Diane McCreary, Region 3, U.S. EPA Library, 3rd Floor, 841 Chestnut Building, 9th & Chestnut Streets, Philadelphia, PA 19107, 215/597–7904

Kathy Piselli, Region 4, U.S. EPA, 345 Courtland Street, NE, Atlanta, GA 30365, 404/347–4216

Cathy Freeman, Region 5, U.S. EPA, Records Center, Waste Management Division 7–J, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604, 312/886–6214

Bart Canellas, Region 6, U.S. EPA, 1445 Ross Avenue, Mail Code 6H–MA, Dallas, TX 75202–2733, 214/655–6740

Steven Wyman, Region 7, U.S. EPA Library, 726 Minnesota Avenue, Kansas City, KS 66101, 913/551–7241

Greg Oberley, Region 8, U.S. EPA, 999 18th Street, Suite 500, Denver, CO 80202–2466, 303/294–7598

Rachel Loftin, Region 9, U.S. EPA, 75 Hawthorne Street, San Francisco, CA 94105, 415/744–2347

David Bennett, Region 10, U.S. EPA, 11th Floor, 1200 6th Avenue, Mail Stop HW–114, Seattle, WA 98101, 206/553–2103

The Headquarters docket for this rule contains HRS score sheets for each proposed site; a Documentation Record for each site describing the information used to compute the score; pertinent information for any site affected by particular statutory requirements or EPA listing policies; and a list of documents referenced in the Documentation Record. Each Regional docket for this rule contains all of the information in the Headquarters docket for sites in that Region, plus the actual reference documents containing the data principally relied upon and cited by EPA in calculating or evaluating the HRS scores for sites in that Region. These reference documents are available only in the Regional dockets. Interested parties may view documents, by appointment only, in the Headquarters or the appropriate Regional docket or copies may be requested from the Headquarters or appropriate Regional docket. An informal written request, rather than a formal request under the Freedom of Information Act, should be the ordinary procedure for obtaining copies of any of these documents.

EPA considers all comments received during the comment period. During the comment period, comments are placed in the Headquarters docket and are available to the public on an "as received" basis. A complete set of comments will be available for viewing in the Regional docket approximately one week after the formal comment period closes. Comments received after the comment period closes will be available in the Headquarters docket and in the Regional docket on an "as received" basis.

Comments that include complex or voluminous reports, or materials prepared for purposes other than HRS scoring, should point out the specific information that EPA should consider and how it affects individual HRS factor values. See *Northside Sanitary Landfill* v. *Thomas*, 849 F.2d 1516 (D.C. Cir. 1988). EPA will make final listing decisions after considering the relevant comments received during the comment period.

In past rules, EPA has attempted to respond to late comments, or when that was not practicable, to read all late comments and address those that brought to the Agency's attention a fundamental error in the scoring of a site. (See, most recently, 57 FR 4824 (February 7, 1992)). Although EPA intends to pursue the same policy with sites in this rule, EPA can guarantee that it will consider only those comments postmarked by the close of the formal comment period. EPA cannot delay a final listing decision solely to accommodate consideration of late comments.

In certain instances, interested parties have written to EPA concerning sites which were not at that time proposed to the NPL. If those sites are later proposed to the NPL, parties should review their earlier concerns and, if still appropriate, resubmit those concerns for consideration during the formal comment period. Site-specific correspondence received prior to the period of formal proposal and comment will not generally be included in the docket.

II. Purpose and Implementation of the NPL

Purpose

The legislative history of CERCLA (Report of the Committee on Environment and Public Works, Senate Report No. 96–848, 96th Cong., 2d Sess. 60 (1980)) states the primary purpose of the NPL:

> The priority lists serve primarily informational purposes, identifying for the States and the public those facilities and sites or other releases which appear to warrant remedial actions. Inclusion of a facility or site on the list does not in itself reflect a judgment of the activities of its owner or operator, it does not require those persons to undertake any action, nor does it assign liability to any person. Subsequent government action in the form of remedial actions or enforcement actions will be necessary in order to do so, and these actions will be attended by all appropriate procedural safeguards.

The purpose of the NPL, therefore, is primarily to serve as an informational and management tool. The identification of a site for the NPL is intended to guide EPA in determining which sites warrant further investigation to assess the nature and extent of the public health and environmental risks associated with the site and to determine what CERCLA remedial action(s), if any, may be appropriate. The NPL also serves to notify the public of sites that EPA believes warrant further investigation. Finally, listing a site may, to the extent potentially responsible parties are identifiable at the time of listing, serve as notice to such parties that the Agency may initiate CERCLA-financed remedial action.

Implementation

After initial discovery of a site at which a release or threatened release may exist, EPA begins a series of increasingly complex evaluations. The first step, the Preliminary Assessment ("PA"), is a low-cost review of existing information to determine if the site poses a threat to public health or the environment. If the site presents a serious imminent threat, EPA may take immediate removal action. If the PA shows that the site presents a threat but not an imminent threat, EPA will generally perform a more extensive study called the Site Inspection ("SI"). The SI involves collecting additional information to better understand the extent of the problem at the site, screen out sites that will not qualify for the NPL, and obtain data necessary to calculate an HRS score for sites which warrant placement on the NPL and further study. EPA may perform removal actions at any time during the process. To date EPA has completed 36,497 PAs and 17,469 SIs.

The NCP at 40 CFR 300.425(b)(1) (55 FR 8845, March 8, 1990) limits expenditure of the Trust Fund for

remedial actions to sites on the NPL. However, EPA may take enforcement actions under CERCLA or other applicable statutes against responsible parties regardless of whether the site is on the NPL, although, as a practical matter, the focus of EPA's CERCLA enforcement actions has been and will continue to be on NPL sites. Similarly, in the case of CERCLA removal actions, EPA has the authority to act at any site, whether listed or not, that meets the criteria of the NCP at 40 CFR 300.415(b)(2) (55 FR 8842, March 8, 1990). EPA's policy is to pursue cleanup of NPL sites using all the appropriate response and/or enforcement actions available to the Agency, including authorities other than CERCLA. The Agency will decide on a site-by-site basis whether to take enforcement or other action under CERCLA or other authorities prior to undertaking response action, proceed directly with Trust Fund-financed response actions and seek to recover response costs after cleanup, or do both. To the extent feasible, once sites are on the NPL, EPA will determine high-priority candidates for CERCLA-financed response action and/or enforcement action through both State and Federal initiatives. EPA will take into account which approach is more likely to accomplish cleanup of the site most expeditiously while using CERCLA's limited resources as efficiently as possible.

Although the ranking of sites by HRS scores is considered, it does not, by itself, determine the sequence in which EPA funds remedial response actions, since the information collected to develop HRS scores is not sufficient to determine either the extent of contamination or the appropriate response for a particular site (40 CFR 300.425(b)(2), 55 FR 8845, March 8, 1990). Additionally, resource constraints may preclude EPA from evaluating all HRS pathways; only those presenting significant risk or sufficient to make a site eligible for the NPL may be evaluated. Moreover, the sites with the highest scores do not necessarily come to the Agency's attention first, so that addressing sites strictly on the basis of ranking would in some cases require stopping work at sites where it was already underway.

More detailed studies of a site are undertaken in the Remedial Investigation/Feasibility Study ("RI/FS") that typically follows listing. The purpose of the RI/FS is to assess site conditions and evaluate alternatives to the extent necessary to select a remedy (40 CFR 300.430(a)(2) (55 FR 8846, March 8, 1990)). It takes into account the amount of hazardous substances, pollutants or contaminants released into the environment, the risk to affected populations and environment, the cost to remediate contamination at the site, and the response actions that have been taken by potentially responsible parties or others. Decisions on the type and extent of response action to be taken at these sites are made in accordance with 40 CFR 300.415 (55 FR 8842, March 8, 1990) and 40 CFR 300.430 (55 FR 8846, March 8, 1990). After conducting these additional studies, EPA may conclude that initiating a CERCLA remedial action using the Trust Fund at some sites on the NPL is not appropriate because of more pressing needs at other sites, or because a private party cleanup is already underway pursuant to an enforcement action. Given the limited resources available in the Trust Fund, the Agency must carefully balance the relative needs for response at the numerous sites it has studied. It is also possible that EPA will conclude after further analysis that the site does not warrant remedial action.

RI/FS at Proposed Sites

An RI/FS may be performed at sites proposed in the **Federal Register** for placement on the NPL (or even sites that have not been proposed for placement on the NPL) pursuant to the Agency's removal authority under CERCLA, as outlined in the NCP at 40 CFR 300.415. Although an RI/FS generally is conducted at a site after it has been placed on the NPL, in a number of circumstances the Agency elects to conduct an RI/FS at a site proposed for placement on the NPL in preparation for a possible Trust Fund-financed remedial action, such as when the Agency believes that a delay may create unnecessary risks to public health or the environment. In addition, the Agency may conduct an RI/FS to assist in determining whether to conduct a removal or enforcement action at a site.

Facility (Site) Boundaries

The NPL does not describe releases in precise geographical terms; it would be neither feasible nor consistent with the limited purpose of the NPL (as the mere identification of releases), for it to do so.

CERCLA section 105(a)(8)(B) directs EPA to list national priorities among the known "releases or threatened releases" of hazardous substances. Thus, the purpose of the NPL is merely to identify releases of hazardous substances that are priorities for further evaluation. Although a CERCLA "facility" is broadly defined to include any area where a hazardous substance release has "come to be located" (CERCLA section 101(9)), the listing process itself is not intended to define or reflect the boundaries of such facilities or releases Of course, HRS data upon which the NPL placement was based will, to some extent, describe which release is at issue. That is, the NPL site would include all releases evaluated as part of that HRS analysis (including noncontiguous releases evaluated under the NPL aggregation policy, described at 48 FR 40663 (September 8, 1983)).

EPA regulations provide that the "nature and extent of the threat presented by a release" will be determined by an RI/FS as more information is developed on site contamination (40 CFR 300.68(d)). During the RI/FS process, the release may be found to be larger or smaller than was originally known, as more is learned about the source and the migration of the contamination. However, this inquiry focuses on an evaluation of the threat posed; the boundaries of the release need not be defined, and in any event are independent of the NPL listing. Moreover, it generally is impossible to discover the full extent of where the contamination "has come to be located" before all necessary studies and remedial work are completed at a site. Indeed, the boundaries of the contamination can be expected to change over time. Thus, in most cases, it will be impossible to describe the boundaries of a release with certainty.

For these reasons, the NPL need not be amended if further research into the extent of the contamination expands the apparent boundaries of the release. Further, the NPL is only of limited significance, as it does not assign liability to any party or to the owner of any specific property. See Report of the Senate Committee on Environment and Public Works, Senate Rep. No. 96–848, 96th Cong., 2d Sess. 60 (1980), quoted at 48 FR 40659 (September 8, 1983). If a party contests liability for releases on discrete parcels of property, it may do so if and when the Agency brings an action against that party to recover costs or to compel a response action at that property.

At the same time, however, the RI/FS or the Record of Decision (which defines the remedy selected, 40 CFR 300.430(f)) may offer a useful indication to the public of the areas of contamination at which the Agency is considering taking a response action, based on information known at that time. For example, EPA may evaluate (and list) a release over a 400-acre area, but the Record of Decision may select a remedy over 100 acres only. This information may be useful to a landowner seeking to sell the other 300

acres, but it would result in no formal change in the fact that a release is included on the NPL. The landowner (and the public) also should note in such a case that if further study (or the remedial construction itself) reveals that the contamination is located on or has spread to other areas, the Agency may address those areas as well.

This view of the NPL as an initial identification of a release that is not subject to constant re-evaluation is consistent with the Agency's policy of not rescoring NPL sites:

> EPA recognizes that the NPL process cannot be perfect, and it is possible that errors exist or that new data will alter previous assumptions. Once the initial scoring effort is complete, however, the focus of EPA activity must be on investigating sites in detail and determining the appropriate response. New data or errors can be considered in that process . . . [T]he NPL serves as a guide to EPA and does not determine liability or the need for response. (49 FR 37081 (September 21, 1984)).

See also *City of Stoughton, Wisc.* v. *U.S. EPA*, 858 F. 2d 747, 751 (D.C. Cir. 1988):

> Certainly EPA could have permitted further comment or conducted further testing [on proposed NPL sites]. Either course would have consumed further assets of the Agency and would have delayed a determination of the risk priority associated with the site. Yet * * * "the NPL is simply a rough list of priorities, assembled quickly and inexpensively to comply with Congress' mandate for the Agency to take action straightaway." Eagle-Picher [Industries v. EPA] II, 759 F. 2d [921,] at 932 [(D.C. Cir. 1985)].

III. Contents of This Proposed Rule

Table 1 identifies the 6 NPL sites in the General Superfund Section and Table 2 identifies the 4 NPL sites in the Federal Facilities Section being proposed in this rule. Both tables follow this preamble. All sites are proposed based on HRS scores of 28.50 or above. The sites in Table 1 and Table 2 are listed alphabetically by State, for ease of identification, with group number identified to provide an indication of relative ranking.

To determine group number, sites on the NPL are placed in groups of 50; for example, a site in Group 4 of this proposal has a score that falls within the range of scores covered by the fourth group of 50 sites on the NPL.

Statutory Requirements

CERCLA section 105(a)(8)(B) directs EPA to list priority sites "among" the known releases or threatened releases of hazardous substances, pollutants, or contaminants, and section 105(a)(8)(A) directs EPA to consider certain enumerated and "other appropriate" factors in doing so. Thus, as a matter of policy, EPA has the discretion not to use CERCLA to respond to certain types of releases. Where other authorities exist, placing sites on the NPL for possible remedial action under CERCLA may not be appropriate. Therefore, EPA has chosen not to place certain types of sites on the NPL even though CERCLA does not exclude such action. If, however, the Agency later determines that sites not listed as a matter of policy are not being properly responded to, the Agency may place them on the NPL.

The listing policies and statutory requirements of relevance to this proposed rule cover sites subject to the Resource Conservation and Recovery Act ("RCRA") (42 U.S.C. 6901–6991i) and Federal facility sites. This policy and requirements are explained below and have been explained in greater detail previously through rulemaking (56 FR 5598, February 11, 1991).

Releases From Resource Conservation and Recovery Act (RCRA) Sites

EPA's policy is that facilities are eligible for NPL listing if they have lost authorization to operate and for which there are additional indications that the owner or operator will be unwilling to undertake corrective action. Authorization to operate may be lost when the interim status of the facility is terminated as a result of a permit denial under RCRA section 3005(c) (54 FR 41004).

Consistent with EPA's NPL/RCRA policy, EPA is proposing to add one site to the General Superfund Section of the NPL, the Aqua-Tech Environmental Inc. (Groce Laboratories) site in Spartanburg County, South Carolina, that operated a RCRA Treatment, Storage and Disposal Facility (TSDF) under interim status. This facility lost its authorization to operate when its RCRA TSDF Part B application was denied. Material has been placed in the public docket documenting this.

Releases From Federal Facility Sites

On March 13, 1989 (54 FR 10520), the Agency announced a policy for placing Federal facility sites on the NPL if they meet the eligibility criteria (e.g., an HRS score of 28.50 or greater), even if the Federal facility also is subject to the corrective action authorities of RCRA Subtitle C. In that way, those sites could be cleaned up under CERCLA, if appropriate.

This rule proposes to add four sites to the Federal Facilities Section of the NPL.

Economic Impacts

The costs of cleanup actions that may be taken at any site are not directly attributable to placement on the NPL. EPA has conducted a preliminary analysis of economic implications of today's proposal to the NPL. EPA believes that the kinds of economic effects associated with this proposal generally are similar to those effects identified in the regulatory impact analysis (RIA) prepared in 1982 for the revisions to the NCP pursuant to section 105 of CERCLA and the economic analysis prepared when amendments to the NCP were proposed (50 FR 5882, February 12, 1985). The Agency believes the anticipated economic effects related to proposing and adding sites to the NPL can be characterized in terms of the conclusions of the earlier RIA and the most recent economic analysis.

Inclusion of a site on the NPL does not itself impose any costs. It does not establish that EPA necessarily will undertake remedial action, nor does it require any action by a private party or determine its liability for site response costs. Costs that arise out of site responses result from site-by-site decisions about what actions to take, not directly from the act of listing itself. Nonetheless, it is useful to consider the costs associated with responding to the sites included in this rulemaking.

The major events that typically follow the proposed listing of a site on the NPL are a search for potentially responsible parties and a remedial investigation/feasibility study (RI/FS) to determine if remedial actions will be undertaken at a site.

Design and construction of the selected remedial alternative follow completion of the RI/FS, and operation and maintenance (O&M) activities may continue after construction has been completed.

EPA initially bears costs associated with responsible party searches. Responsible parties may bear some or all the costs of the RI/FS, remedial design and construction, and O&M, or EPA and the States may share costs.

The State cost share for site cleanup activities has been amended by SARA. For privately-owned sites, as well as at publicly-owned but not publicly-operated sites, EPA will pay for 100% of the costs of the RI/FS and remedial planning, and 90% of the costs associated with remedial action. The State will be responsible for 10% of the remedial action. For publicly-operated sites, the State cost share is at least 50% of all response costs at the site, including the RI/FS and remedial design and construction of the remedial action

selected. After the remedy is built, costs fall into two categories:

—For restoration of ground water and surface water, EPA will share in startup costs according to the criteria in the previous paragraph for 10 years or until a sufficient level of protectiveness is achieved before the end of 10 years.

—For other cleanups, EPA will share for up to 1 year the cost of that portion of response needed to assure that a remedy is operational and functional. After that, the State assumes full responsibilities for O&M.

In previous NPL rulemakings, the Agency estimated the costs associated with these activities (RI/FS, remedial design, remedial action, and O&M) on an average per site and total cost basis. EPA will continue with this approach, using the most recent cost estimates available; the estimates are presented below. However, there is wide variation in costs for individual sites, depending on the amount, type, and extent of contamination. Additionally, EPA is unable to predict what portions of the total costs responsible parties will bear, since the distribution of costs depends on the extent of voluntary and negotiated response and the success of any cost-recovery actions.

Cost category	Average total cost per site [1]
RI/FS	1,350,000
Remedial Design	1,260,000
Remedial Action	[3] 21,960,000
New present value of O&M [2]	3,770,000

Source: Office of Program Management, Office of Emergency and Remedial Response, U.S. EPA, Washington, DC.

[1] 1993 U.S. Dollars

[2] Assumes cost of O&M over 30 years, $400,000 for the first year and 10% discount rate.

[3] Includes State cost-share.

Costs to the States associated with today's proposed rule are incurred when the sites are finalized and arise from the required State cost-share of: (1) 10% of remedial actions and 10% of first-year O&M costs at privately-owned sites and sites that are publicly-owned but not publicly-operated; (2) at least 50% of the remedial planning (RI/FS and remedial design), remedial action, and first-year O&M costs at publicly-operated sites; and (3) States will assume the cost for O&M after EPA's period of participation. Using the budget projections presented above, the cost to the States of undertaking Federal remedial planning and actions, but excluding O&M costs, would be approximately $21 million. State O&M costs cannot be accurately determined because EPA, as noted above, will pay O&M costs for up to 10 years for restoration of ground water and surface water, and it is not known if the site will require this treatment and for how long. Assuming EPA involvement for 10 years is needed, State O&M costs would be approximately $16 million.

Placing a site on the proposed or final NPL does not itself cause firms responsible for the site to bear costs. Nonetheless, a listing may induce firms to clean up the sites voluntarily, or it may act as a potential trigger for subsequent enforcement or cost-recovery actions. Such actions may impose costs on firms, but the decisions to take such actions are discretionary and made on a case-by-case basis. Consequently, precise estimates of these effects cannot be made. EPA does not believe that every site will be cleaned up by a responsible party. EPA cannot project at this time which firms or industry sectors will bear specific portions of the response costs, but the Agency considers: the volume and nature of the waste at the sites; the strength of the evidence linking the wastes at the site to the parties; the parties' ability to pay; and other factors when deciding whether and how to proceed against the parties.

Economy-wide effects of an amendment to the NPL are aggregations of efforts on firms and State and local governments. Although effects could be felt by some individual firms and States, the total impact of this amendment on output, prices, and employment is expected to be negligible at the national level, as was the case in the 1982 RIA.

Benefits

The real benefits associated with today's amendment are increased health and environmental protection as a result of increased public awareness of potential hazards. In addition to the potential for more Federally-financed remedial actions, expansion of the NPL could accelerate privately-financed, voluntary cleanup efforts. Listing sites as national priority targets also may give States increased support for funding responses at particular sites.

As a result of the additional CERCLA remedies, there will be lower human exposure to high-risk chemicals, and higher-quality surface water, ground water, soil, and air. These benefits are expected to be significant, although difficult to estimate in advance of completing the RI/FS at these sites.

IV. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866 review.

V. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act of 1980 requires EPA to review the impacts of this action on small entities, or certify that the action will not have a significant impact on a substantial number of small entities. By small entities, the Act refers to small businesses, small government jurisdictions, and nonprofit organizations.

While this rule proposes to revise the NPL, an NPL revision is not a typical regulatory change since it does not automatically impose costs. As stated above, adding sites to the NPL does not in itself require any action by any party, nor does it determine the liability of any party for the cost of cleanup at the site. Further, no identifiable groups are affected as a whole. As a consequence, impacts on any group are hard to predict. A site's inclusion on the NPL could increase the likelihood of adverse impacts on responsible parties (in the form of cleanup costs), but at this time EPA cannot identify the potentially affected businesses or estimate the number of small businesses that might also be affected.

The Agency does expect that placing the sites in this proposed rule on the NPL could significantly affect certain industries, or firms within industries, that have caused a proportionately high percentage of waste site problems. However, EPA does not expect the listing of these sites to have a significant economic impact on a substantial number of small businesses.

In any case, economic impacts would occur only through enforcement and cost-recovery actions, which EPA takes at its discretion on a site-by-site basis. EPA considers many factors when determining enforcement actions, including not only a firm's contribution to the problem, but also its ability to pay. The impacts (from cost recovery) on small governments and nonprofit organizations would be determined on a similar case-by-case basis.

For the foregoing reasons, I hereby certify that this proposed rule would not have a significant economic impact on a substantial number of small entities. Therefore, this proposed regulation does not require a regulatory flexibility analysis.

NATIONAL PRIORITIES LIST, PROPOSED RULE #17, GENERAL SUPERFUND SECTION

State	Site name	City/county	NPL Gr[1]
FL	Escambia Wood—Pensacola	Escambia Co	5
LA	Agriculture Street Landfill	New Orleans	5
MS	Texas Eastern Kosciusko Compressor Station	Attala Co	5
MT	Burlington Northern Livingston Shop Complex	Livingston	5
OR	Reynolds Metals	Troutdale	1
SC	Aqua-Tech Environmental Inc. (Groce Laboratories)	Spartanburg Co	5

Number of Sites Proposed to General Superfund Section: 6.

[1] Sites are placed in groups (Gr) corresponding to groups of 50 on the final NPL.

NATIONAL PRIORITIES LIST, PROPOSED RULE #17, FEDERAL FACILITIES SECTION

State	Site name	City/county	NPL Gr[1]
NC	Cherry Point Marine Corps Air Station	Havelock	1
PA	Willow Grove Naval Air & Air Reserve Station	Willow Grove	5
SC	Parris Island Marine Corps Recruit Depot	Beaufort	5
TN	Arnold Engineering Development Center (USAF)	Coffee Co. & Franklin Co..	5

Number of Sites Proposed to Federal Facilities Section: 4.

[1] Sites are placed in groups (Gr) corresponding to groups of 50 on the final NPL.

List of Subjects in 40 CFR Part 300

Air pollution control, Chemicals, Hazardous materials, Intergovernmental relations, Natural resources, Oil pollution, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control, Water supply.

Authority: 42 U.S.C. 9605; 42 U.S.C. 9620; 33 U.S.C. 1321(c)(2); E.O. 11735, 3 CFR, 1971–1975 Comp., p. 793; E.O. 12580, 3 CFR, 1987 Comp., p. 193.

Dated: August 16, 1994.

Elliott P. Laws,

Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 94–20549 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 555

[Docket 94–69; Notice 1]

Temporary Exemption From Motor Vehicle Safety Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of request for comments.

SUMMARY: This document requests comments on the recommendation by the National Performance Review that the number of motor vehicles which may be exempted from compliance with the Federal motor vehicle safety standards (FMVSSs) on the basis that they possess innovative safety features be increased from the 2,500 per year presently specified by statute. The recommendation is based on the belief that an increase may encourage vehicle manufacturers to seek exemptions allowing them to introduce safety innovations.

DATES: The closing date for comments is October 24, 1994.

ADDRESSES: Comments should refer to the docket number and the notice number, and be submitted to: Docket Section, room 5109, Nassif Building, 400 Seventh Street, SW, Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.).

FOR FURTHER INFORMATION CONTACT: Noble Bowie, Office of Plans and Programs, NHTSA (202–366–2549).

SUPPLEMENTARY INFORMATION:

Existing Exemption Authority

NHTSA is directed by 49 U.S.C. 30111 (formerly 15 U.S.C. 1392) to issue FMVSSs to reduce the number and severity of vehicle crashes and to reduce the likelihood that deaths and injuries will occur in those crashes. In recognition of the need to provide exemptions from the FMVSSs in special, limited circumstances, NHTSA requested Congress in 1972 to give it express authority for this purpose. The authority was intended to, among other things, permit the agency to grant exemptions to permit vehicle manufacturers to allow them to incorporate new safety features into their vehicles.

In response, Congress enacted legislation later that same year to authorize the agency to exempt a motor vehicle manufacturer from any FMVSS based on any one of four findings. 49 U.S.C. 30113 (formerly section 123 of the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. 1410). One was a finding that "the exemption would make easier the development or field evaluation of a new motor vehicle safety feature providing a safety level at least equal to the safety level of the standard." Such an exemption may be granted for a period that does not exceed two years (subject to renewal). The exemption may not cover "more than 2,500 vehicles to be sold in the United States in any 12-month period". (49 U.S.C. 30113 (d) and (e)).

There is scant legislative history regarding the congressional intentions underlying this exemption provision.

A single sentence of explanation appeared in floor statements made on October 6, 1972 by Senator Hartke:

> The purpose of this provision is to enable manufacturers to experiment with innovative safety concepts but not endanger the health and safety of the motoring public.

(See pages S34207–34209)

In issuing FMVSSs, the agency drafts them to be as performance oriented as possible to minimize the need to amend them to accommodate future technological advances. If a vehicle manufacturer nevertheless finds that a provision of an existing standard has the effect of prohibiting a new device, it may petition the agency to amend that provision so as to allow the device. At

any given time, the agency is conducting numerous rulemaking proceedings in response to such petitions. In a very few cases since 1972, vehicle manufacturers have petitioned for exemption under the provision relating to innovative safety features. Indeed, exemption on the grounds of an innovative safety feature has been the least frequently used of the four statutory bases upon which a manufacturer may submit an exemption petition.

National Performance Review

This notice responds to a recommendation by The National Performance Review (NPR), which was chaired by the Vice President of the United States. The NPR reviewed NHTSA's statutes and regulations, and recommended in its report, "From Red Tape to Results," that the number of vehicles that may be covered by a safety exemption be raised. For the benefit of readers unfamiliar with this particular NPR recommendation, the agency has set forth below the relevant passages from the accompanying Report of the National Performance Review—September 1993 (pp. 23–24):

Background

Technology and consumer preferences often change faster than the rulemaking process of the National Highway Traffic Safety Administration (NHTSA) can move. Today, for example, automotive safety is an important concern of consumers. Manufacturers who can deliver the safety features their customers want are at a sales advantage. Manufacturers, therefore, have a financial incentive for investing time and money in new or improved safety features—if they thought they could make their way through the NHTSA approval process in time to capitalize on the current trends in consumer preference.

Current enabling legislation and the NHTSA rulemaking processes, however, are too encumbering and time consuming to enable NHTSA to turn short-term consumer trends into long-term safety advances. The cost and time required to assemble the needed justification and the average two-year duration of the rulemaking process can inhibit manufacturers from introducing safety improvements. As a result, consumers have to wait two years or more before improvements reach the market.

Although NHTSA can grant a temporary exemption from standards to help advance new safety systems, no more than 2,500 vehicles can be sold per year for each exemption granted. This number is too low to provide manufacturers with sufficient economic and marketing incentives and to allow extensive, real-world evaluations.

Actions

1. Legislation should be enacted to raise the current 2,500-vehicle limit on exemptions.

NHTSA should consider all factors that are relevant to expanding the exemption provision into a more effective mechanism for encouraging safety innovations. NHTSA should then determine what higher exemption authority is desirable and draft legislation for submission to Congress at the beginning of the next session (January 1995).

Legislation should be enacted to authorize NHTSA to grant such exemptions after public notice and comment.

NHTSA should grant exemptions only after it is satisfied that a manufacturer will thoroughly evaluate the actual "on-road" benefits (or problems) of the exempted safety system. NHTSA should ensure that the manufacturers carry out the evaluation and help them to do this.

Implications

By increasing the vehicle limits, NHTSA will promote cooperation between government and industry, motivate industry to introduce new safety devices because of the economic advantage of selling innovative safety features, enhance support from industry and consumers for possible safety improvements, and introduce some safety advances to the marketplace sooner than might occur through lengthy, costly, and contentious rulemaking.

Fiscal Impact

Both industry and government will be able to reduce costs associated with research and evaluation. NHTSA will also realize a reduction in staff resources currently devoted to rulemaking; however, the specific fiscal implications will depend on the nature and frequency of exemptions and cannot be estimated.

Issues for Public Comment

In order to assess the need for legislation and to prepare a request for it by January 1995, if such is warranted, NHTSA requests information that will assist it in identifying ways in which its exemption authority could be amended to encourage manufacturers to seek exemptions in order to incorporate new safety technologies in production vehicles at the earliest time in advance of possible amendments of relevant FMVSSs. Two particular concerns underlie the NPR report: (1) the minimum size of production runs of new safety features necessary to be economically feasible; and (2) the minimum number of vehicles required to provide statistically significant data for evaluation. Therefore, NHTSA asks vehicle manufacturers to quantify these two minima, and explain the basis for their responses. Manufacturers and other commenters should submit documents, analyses, or other data that are germane to these concerns.

NHTSA also requests comments on the following issues—

1. Whether impediments exist, such as liability concerns, that discourage vehicle manufacturers from using the exemption process to evaluate safety innovations.

2. The identity of any specific existing or anticipated safety innovations whose introduction might be prohibited by an existing or proposed FMVSS and for which vehicle manufacturers would apply for exemption if the number of vehicles covered were increased, and/or if the exemption term were longer.

3. The level to which the number of exempted vehicles would have to be increased and/or the extent to which exemption term would have to be lengthened in order to encourage vehicle manufacturers to apply for temporary exemptions.

4. Whether the number of exempted vehicles and/or term should be left to the Administrator's discretion, instead of being statutorily specified as at present.

5. Under expanded exemption authority, how the agency should assess, in advance of the results of an on-the-road evaluation, the likelihood that an innovative safety feature will yield equal or superior safety benefits. The agency is mindful of the concern expressed in the legislative history that the issuance of exemptions for innovative safety features should not endanger the health and safety of the motoring public. If the number of vehicles that can be covered by in a single exemption is increased, there could be a commensurate increase in the potential adverse consequences of an erroneous judgment by the agency that an innovative feature will provide safety benefits that equal or exceed those of complying features.

6. Whether there are other amendments to NHTSA's existing statutory authority, 49 U.S.C. Chapter 301—Motor Vehicle Safety (formerly 15 U.S.C. 1381 et seq., the National Traffic and Motor Vehicle Safety Act) which would encourage automotive safety innovations without compromising safety.

7. The validity of the assumptions underlying NPR's analysis and conclusions.

It is requested but not required that ten copies of each comment be submitted. No comments may exceed 15 (fifteen) pages in length (49 CFR 553.21). Necessary attachments may be appended to submissions without regard to the 15-page limit.

All comments received before the close of business on the comment closing date listed above will be considered and will be available for examination in the docket room and the above address both before and after that date. To the extent possible, comments filed after the closing date will be

considered. The agency will continue to file relevant information as it becomes available. It is recommended that interested persons continue to examine the docket for new material. Those commenters desiring to be notified upon receipt of their comments by the docket section should include a self-addressed, stamped postcard in the envelope with their comments. Upon receipt of their comments, the docket supervisor will return the postcard by mail.

Authority: 49 U.S.C. 30117.

Issued on: August 16, 1994.

Donald C. Bischoff,

Associate Administrator for Plans and Policy.

[FR Doc. 94–20635 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–59–P

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1048

[Ex Parte No. MC–37 (Sub-No. 43)]

McAllen, TX Commercial Zone—Passenger Operations

AGENCY: Interstate Commerce Commission.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The City of McAllen, TX (petitioner) has filed a petition seeking withdrawal of the commercial zone exemption provided in 49 U.S.C. 10526(b) so as to subject the local operations of motor passenger carriers that traverse the United States-Mexico border within the commercial zone of McAllen (and, if appropriate, other cities similarly situated) to the regulatory requirements normally applicable to the routes, rates, and services of motor carriers of passengers in interstate and foreign commerce. Petitioner alleges that the requested relief is necessary to alleviate problems of public safety, traffic congestion, and unfair competition by exempt foreign passenger carriers operating within the commercial zones of border municipalities. Petitioner alleges that these problems have been exacerbated by the recent passage of the North American Free Trade Agreement (NAFTA). Comments in support of the petition were filed by Valley Transit Company, Inc., the Railroad Commission of Texas, and the Attorney General of the State of Texas. Following receipt of public comments resulting from this advance notice of proposed rulemaking (ANPR), specific changes to our commercial zone regulations would be proposed for comment if we proceed to the notice of proposed rulemaking stage.

DATES: Any person interested in participating in this proceeding as a party of record may file comments by October 24, 1994.

ADDRESSES: Send an original and 10 copies of pleadings referring to Ex Parte No. MC–37 (Sub-No. 43) to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5610. [TDD for hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: For a more detailed discussion of the current regulations, the issues raised by the petition, and the information that we seek, see the Commission's separate decision. To obtain a copy of this decision, write to, call, or pick up in person from: Office of the Secretary, Room 2215, Interstate Commission, Washington, D.C. 20423. Telephone: (202) 927–7428. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Regulatory Flexibility Analysis

Because this is not a notice of proposed rulemaking within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we need not conduct now an examination of its impact on small businesses pursuant to that Act. Nevertheless, we welcome any comments regarding the small entities considerations embodied in that Act. If we decide to issue a notice of proposed rulemaking, we will conduct an appropriate Regulatory Flexibility Act examination.

Environmental and Energy Considerations

Issuance of this ANPR will not significantly affect either the quality of the human environment or the conservation of energy resources because we merely seek information and are not proposing any change in current rules or policy.

We preliminarily conclude that, even if we subsequently decide to grant the relief sought by petitioner, an environmental assessment would not be necessary under our regulations because the proposed action would not result in changes in carrier operations that exceed the thresholds established in our regulations. See 49 CFR 1105.6(c)(2). Nonetheless, we invite comments on the environmental and energy impacts of petitioner's proposal.

List of Subjects in 49 CFR Part 1048

Commercial zones, Motor carriers.

Authority: 49 U.S.C. 10321 and 10526; 5 U.S.C. 553.

Decided: August 11, 1994.

By the Commission, Chairman McDonald, Vice Chairman Phillips, and Commissioners Simmons and Morgan.

Vernon A. Williams,

Acting Secretary.

[FR Doc. 94–20653 Filed 8–22–94; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AC42

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for Lesquerella Perforata (Spring Creek Bladderpod)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to determine endangered status for Spring Creek bladderpod pursuant to the Endangered Species Act (Act) of 1973, as amended. This rare plant is presently known from only a limited area within Tennessee's Central Basin. It is threatened by habitat alteration; residential, commercial, or industrial development; livestock-grazing; conversion of its limited habitat to pasture; and habitat encroachment by woody vegetation and herbaceous perennials. This proposal, if made final, would extend the protection and recovery provisions of the Act to Spring Creek bladderpod.

DATES: Comments from all interested parties must be received by October 24, 1994. Public hearing requests must be received by October 7, 1994.

ADDRESSES: Comments, materials, and requests for a public hearing concerning this proposal should be sent to the Field Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 330 Ridgefield Court, Asheville, North Carolina 28806. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr Robert R. Currie at the above address (704/665–1195, Ext. 224).

SUPPLEMENTARY INFORMATION:

Background

Lesquerella perforata (Spring Creek bladderpod), described by R. C. Rollins

(Rollins 1952), occurs within a small area in Wilson County in the vicinity of Lebanon, Tennessee. This winter annual is 2 to 4 decimeters (8 to 16 inches) tall. Its auriculate leaves are oblong to ovate in shape. The flowers have petals that are 7 to 10 millimeters (0.3 to 0.4 inches) long and are white to lavender in color. It has a broadly ovoid-shaped fruit that is hairless on the outside and densely pubescent on the inside. An internal partition between the two halves of the fruit is "perforated" or missing.

Lesquerella perforata is a winter annual that germinates in early fall, over-winters as small rosettes of leaves, and flowers the following spring. Flowering usually occurs in March and April. Soon after the flowers wither, the fruit matures and the plants die. The fruits split open and the enclosed seeds fall to the ground and lie dormant until the fall, when the cycle starts over again. If conditions are not suitable for germination the following fall, the seeds can remain dormant (but viable) for several years (Kral 1983, Rollins 1952, Rollins 1955, Baskin and Baskin 1990).

This species is typically found growing on floodplains. It requires annual disturbance in order to complete its life cycle. Historically, this disturbance was probably provided by periodic flooding of the streams along which it occurs. This flooding is thought to have removed the perennial grasses and woody plants that quickly invade the floodplains without regular natural or artificial disturbance. Cultivation of annual crops, such as corn, provides an excellent means of artificially maintaining the habitat, provided there is no fall plowing, and herbicide use is limited. No-till farming techniques are believed to adversely affect the species because of the extensive use of herbicides required to successfully implement the technique. Row-crop cultivation, which avoids the use of fall plowing and delays spring plowing until the majority of the plants have set fruit, does not seem to adversely affect the species (Somers *et al.* 1993; Shea *et al.* 1993; Somers, Massachusetts Natural Heritage and Endangered Species Program, personal communication, 1992).

Lesquerella perforata is known from four populations consisting of 13 extant sites in Wilson County, Tennessee. Three additional sites no longer support the species. One of the extant populations occurs along Spring Creek and consists of five groups of plants. Another, consisting of four groups of plants, is found along Lower Bartons Creek. Two sites are located farther upstream and are designated the Middle Bartons Creek population. The fourth population consists of two sites and is located along a tributary of Bartons Creek. All of the known sites for the species are found within a few miles of each other; with only one exception, sites are within the floodplains of Spring and Bartons Creeks or within the floodplain of a Bartons Creek tributary. The only nonfloodplain location is within a glade-like area slightly above the floodplain of Spring Creek (Somers *et al.* 1993). All of the known sites supporting *L. perforata* are privately owned, and none are protected through cooperative management agreements with the State or the Service.

The following site specific information is from Somers et al. (1993).

Spring Creek Population: Site 1 is the largest known site for the species and is also the *L. perforata* type locality. In 1992 the site supported over 100,000 individuals. Although this is a significant population, plants were much denser, and the area supporting them was larger, in 1980. Site 2 is a field that supported about 500 plants in 1992. Site 3 supported 25,000 to 50,000 plants in 1992. Site 4 is a small area, about 90 feet long and 43 feet wide, supporting between 1,000 and 5,000 in 1992. Site 5 is the only non-floodplain site for the species and was discovered during the 1992 field work to update the status of *L. perforata*. The area is a triangular-shaped glade that is about 150 feet long and about 100 feet wide at its widest point. The site was estimated to support between 500 and 1,000 plants in 1992.

Lower Bartons Creek Population: Site 6 is a small site that supported about 1,000 plants in 1992. Site 7 is a small site that supported two small clumps (30 feet by 5 feet) of the species in 1992. Site 8 is a small site that supported only a few plants in 1992. Site 9 is a medium-sized site that supported about 10,000 plants in 1992.

Middle Bartons Creek Population: Site 10 is a small tract in an industrialized area near Lebanon that supported about 600 plants in 1992. Site 11 is near Site 10 but supports a larger colony of about 5,000 plants.

Bartons Creek Tributary Population: Site 12 is located along 1,000 feet of the floodplain of an ephemeral tributary of Bartons Creek. In 1992 it supported about 450 plants. Site 13 is a small area located near Site 12; it contains only a few individuals. In 1992 the area was overgrown with dense herbaceous growth.

Federal government actions on this species began with section 12 of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*), which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. This report, designated as House Document No. 94–51, was presented to Congress on January 9, 1975. On July 1, 1975, the Service published a notice (40 FR 27823) that formally accepted the Smithsonian report as a petition within the context of section 4(c)(2) (now section 4(b)(3)) of the Act. By accepting this report as a petition, the Service also acknowledged its intention to review the status of those plant taxa named within the report. *Lesquerella perforata* was included in the Smithsonian report and the July 1, 1975, notice of review. On June 16, 1976, the Service published a proposed rule (41 FR 24523) to determine approximately 1,700 vascular plant taxa to be endangered species pursuant to Section 4 of the Act; *L. perforata* was included in this proposal.

The 1978 amendments to the Act required that all proposals over 2 years old be withdrawn. On December 10, 1979 (44 FR 70796), the Service published a notice withdrawing plants proposed on June 16, 1976. *Lesquerella perforata* was included as a category 1 species in the revised notice of review for native plants published on December 15, 1980 (45 FR 82480). Category 1 species are those for which the Service has information that indicates that proposing to list them as endangered or threatened is appropriate. This species was maintained in category 1 when the notice of review for native plants was revised in 1983 (48 FR 53640) and again in 1985 (50 FR 39526), 1990 (55 FR 6184), and 1993 (58 FR 51144).

The Service funded a survey in 1992 to update the status information on *L. perforata*. A final report was received in February 1993. During the 1992 and 1993 field seasons, personnel with the Tennessee Department of Environment and Conservation conducted extensive inventories of all the known and potential sites for this species.

All plants included in the comprehensive plant notices are treated as under petition. Section 4(b)(3)(B) of the Act, as amended in 1982, requires the Secretary to make certain findings on pending petitions within 12 months of their receipt. Section 2(b)(1) of the 1982 amendments further requires that all petitions pending on October 13, 1982, be treated as having been newly submitted on that date. This was the case for *L. perforata* because of the acceptance of the 1975 Smithsonian report as a petition. Each year between 1983 and 1993 the Service found that the petitioned listing of this species was warranted but precluded by other listing actions of a higher priority and that

additional data on vulnerability and threats were still being gathered. Publication of this proposal constitutes the final 1-year finding.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Act and regulations (50 CFR Part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal Lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Lesquerella perforata* Rollins (Spring Creek bladderpod) are as follows:

A. The present or threatened destruction, modification, or curtailment of its habitat or range

Most of the known locations for this species are threatened by the encroachment of more competitive herbaceous vegetation and/or woody plants. Active management is required to ensure that the species continues to survive at all sites. Direct destruction of habitat for commercial, residential, or industrial development is the most significant threat to the species at this time. *Lesquerella perforata* is threatened by the loss of habitat through conversion of land to uses other than cultivation of annual crops. Historically, its habitat was maintained by natural events, such as flooding. Annual crop production is apparently the primary mechanism by which essential habitat is now maintained. Residential, business, or industrial construction removes the species' preferred habitat directly or creates an environment where succession is allowed to proceed or more competitive plant species are intentionally established or are allowed to invade the area. Conversion of sites to pasture or other uses that maintain a perennial cover crop are a significant threat. In order for this annual plant to complete its life cycle each year, it is essential that the sites not be plowed or disked after the seeds have germinated in the fall and that spring plowing and planting be delayed until the plants have matured in the spring. This requirement is easily met through the production of crops such as corn, provided that traditional cultivation methods are used. Use of no-till cultivation techniques does not appear to maintain the species' habitat. This is probably because of the lack of physical disturbance of the soil and the dependence upon herbicides that characterize the technique (Shea *et al.* 1993, Somers *et al.* 1993).

B. Overutilization for commercial, recreational, scientific, or educational purposes

There is little or no commercial trade in *Lesquerella perforata* at this time. Most populations are very small and cannot support the collection of plants for scientific or other purposes. Inappropriate collecting for scientific purposes or as a novelty is a threat to the species.

C. Disease or predation

Disease and predation are not known to be factors affecting the continued existence of this species at this time.

D. The Inadequacy of Existing Regulatory Mechanisms

Lesquerella perforata is listed as an endangered plant in Tennessee under that State's Rare Plant Protection and Conservation Act. This law regulates the sale of endangered plants and prohibits anyone from knowingly taking an endangered plant without the permission of the landowner or land manager.

Should this species be added to the Federal list of endangered and threatened plants, additional protection from taking will be provided when the taking is in violation of any State law, including State trespass laws. Protection from inappropriate commercial trade would also be provided.

E. Other Natural or Manmade Factors Affecting its Continued Existence

None are known at this time.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Lesquerella perforata* as an endangered species. This species is faced with imminent threats from loss of habitat to development and other uses incompatible with the species' survival, and by competing vegetation that is no longer controlled by natural flood regimes. These threats are compounded due to the species' restricted range and limited number of populations. In accordance with the definitions for endangered and threatened species found in section 3(6) and (19) of the Act, endangered is the most appropriate classification for *L. perforata.*

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that, to the maximum extent prudent and determinable, the Secretary designate any habitat of a species, which is considered to be critical habitat, at the time the species is determined to be endangered or threatened. Title 50, Part 424 of the Code of Federal Regulations, Section 424.12(1) states that designation of critical habitat is not prudent when one or both of the following situations exist: (i) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species, or (ii) Such designation of critical habitat would not be beneficial to the species. Both situations apply to *L. perforata.*

Publication of critical habitat maps would increase public interest and possibly lead to additional threats for the species from collecting and vandalism. This species occurs at a limited number of sites, and most are fairly accessible. Publication of critical habitat descriptions and maps would make *Lesquerella perforata* more vulnerable and would increase enforcement problems.

Critical habitat also would not be beneficial in terms of adding additional protection for this species under Section 7 of the Act. Regulations promulgated for the implementation of Section 7 provide for both a "jeopardy" standard and a "destruction or adverse modification" of critical habitat standard. Because of the highly limited distribution of this species, any Federal action that would destroy or have any significant adverse affect on its habitat would likely result in a jeopardy biological opinion under Section 7. Under these conditions, no additional benefits would accrue from designation of critical habitat that would not be available through listing alone.

The owners and managers of all the known populations of this species will be made aware of the plants' locations and of the importance of protecting the species and its habitat. Should Federal involvement occur, habitat protection will be addressed through the Section 7 consultation process, utilizing the jeopardy standard. Protection of the species' habitat will also be addressed through the recovery process. No additional benefits would result from a determination of critical habitat. Therefore, the Service concludes that it is not prudent to designate critical habitat for *Lesquerella perforata.*

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition,

recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in the destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

All of the known *Lesquerella perforata* populations are on privately owned land where there is no known or anticipated Federal involvement at the present time.

The Act and its implementing regulations found at 50 CFR 17.61, 17.62, and 17.63 set forth a series of general prohibitions and exceptions that apply to all endangered plants. All trade prohibitions of Section 9(a)(2) of the Act, implemented by 50 CFR 17.61, would apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale this species in interstate or foreign commerce, or to remove and reduce to possession the species from areas under Federal jurisdiction. In addition, for endangered plants, the 1988 amendments (Pub. L. 100–478) to the Act prohibit the malicious damage or destruction on Federal lands and the removal, cutting, digging up, or damaging or destroying of endangered plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions apply to agents of the Service and State conservation agencies.

The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened species under certain circumstances. It is anticipated that few trade permits would ever be sought or issued because the species is not common in cultivation or in the wild. Requests for copies of the regulations on listed plants and inquiries regarding prohibitions and permits should be addressed to the U.S. Fish and Wildlife Service, Attention: Endangered and Threatened Species Permits, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (404/679–4000).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning these proposed rules are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Lesquerella perforata;*

(2) Tthe location of any additional populations of *Lesquerella perforata* and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) Additional information concerning the range and distribution of this species; and

(4) Current or planned activities in the subject area and their possible impacts on *Lesquerella perforata.*

Final promulgation of the regulations on *Lesquerella perforata* will take into consideration the comments and any additional information received by the Service, and such communications may lead to the adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of this proposal. Such requests must be made in writing and addressed to the Field Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 330 Ridgefield Court, Asheville, North Carolina 28806.

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

Baskin, J.M., and C.C. Baskin. 1990. Seed Germination Biology of the Narrowly Endemic Species *Lesquerella stonensis* (Brassicaceae). Plant Species Biol. 5:205–213.

Kral, R. 1983. A Report on Some Rare, Threatened, or Endangered Forest-related Vascular Plants of the South. USDA, Forest Service Tech. Pub. R8–TP2, Vol. 1. 718 pp.

Rollins, R.C. 1952. Some Crucifers of the Nashville Basin, Tennessee. Rhodora 54:182–192.

Rollins, R.C. 1955. The Auriculate-leaved Species of *Lesquerella* (Cruciferae). Rhodora 57:241–264.

Somers, P., A. Shea, and A. McKerrow. 1993. Status Survey Report on *Lesquerella perforata* Rollins (Spring Creek Bladderpod). Unpublished report to the Asheville Field Office, U.S. Fish and Wildlife Service, Asheville, NC. 81 pp.

Author

The primary author of this proposed rule is Mr. Robert R. Currie, Asheville Field Office, U.S. Fish and Wildlife Service, 330 Ridgefield Court, Asheville, North Carolina 28806 (704/665–1195, Ext. 224).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Section 17.12(h) is amended by adding the following, in alphabetical order under Brassicaceae, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
*	*	*	*	*	*	*
Brassicaceae—Mustard family:						
*	*	*	*	*	*	*
Lesquerella perforata	Spring Creek bladderpod	U.S.A. (TN)	E		NA	NA
*	*	*	*	*	*	*

Dated: July 28, 1994.

Mollie H. Beattie,

Director, Fish and Wildlife Service.

[FR Doc. 94–20596 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 59, No. 162
Tuesday, August 23, 1994

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Request for Public Applications for the U.S.-Canada Joint Commission on Grains

AGENCY: Foreign Agricultural Service.
ACTION: Notice of request for written applications.

SUMMARY: This notice describes the application procedures for members of the public volunteering for service on the Commission.

DATES: Applications must be received at the address below by 5 p.m., EDT, August 25, 1994.

ADDRESSES: Deputy Administrator, International Trade Policy, Foreign Agricultural Service, United States Department of Agriculture, Ag Box 1020, Washington, DC 20250–1020 (Applications can also be faxed to 202–720–0069).

FOR FURTHER INFORMATION CONTACT: Len Condon, Deputy Assistant U.S. Trade Representative, Office of the U.S. Trade Representative, room 419, 600 17th Street, NW., Washington, DC 20506, Telephone: (202) 395–5006 or Henry Schmick, International Trade Policy, U.S. Department of Agriculture, Foreign Agricultural Service, Ag Box 1024, Washington, DC 20250–1024, Telephone: (202) 720–1336

SUPPLEMENTARY INFORMATION: As provided for in the recent Memorandum of Understanding between Canada and the United States, a Joint Commission on Grains will be established to examine all aspects of the two countries' respective marketing and support systems for all grains and the effect of those systems on the Canadian and U.S. markets and on competition between the two countries in third country markets. The objective of the Commission will be to make recommendations to assist the two Governments in reaching long-term solutions to existing problems in the grain sector.

Three to five individuals will be selected to represent the United States on the Commission. The Canadian Government will select an equal number to represent Canada. The members of the Commission will be named by September 1, 1994. The Commission is expected to complete its preliminary report, with recommendations to both Governments, by May 1, 1995. The Commission will remain in operation through July 31, 1995.

Application Format

Candidates must submit a written application no longer than two type written pages to the Deputy Administrator, International Trade Policy, Foreign Agricultural Service, United States Department of Agriculture, Ag Box 1020, Washington, DC 20250–1020; FAX (202) 720–0069. Include the applicant's name, mailing address, telephone number, and a short statement of qualifications and/or resume.

Selection Criteria

The United States Department of Agriculture and the Office of United States Trade Representative will select three to five individuals who are expected to represent the broad range of interests involved in the grains issues, invest significant personal time, and effectively communicate the final recommendations to all interested parties.

Compensation

The U.S. members of the Commission will not be paid a salary, or any other compensation, for their service on the Commission. Members will be reimbursed for their travel and per diem expenses at the official U.S. Government rate, in accordance with all applicable travel regulations.

Time and Travel Requirement

The time required to serve on this Commission will be extensive. Applicants should be fully prepared for a demanding schedule, which may include travel to locations in Canada and the United States.

Signed at Washington, DC, August 17, 1994.

Lynnett Wagner,
Acting Administrator, Foreign Agricultural Service.

[FR Doc. 94–20638 Filed 8–22–94; 8:45 am]
BILLING CODE 3410–10–M

DEPARTMENT OF DEFENSE

Department of the Army

Availability for Exclusive, Partially Exclusive or Nonexclusive Licensing of U.S. Patent Concerning the Use of a Tape Indicator System for In-Situ Detection and Determination of Soil Contaminants

AGENCY: U.S. Army Engineers Waterways Experiment Station, DOD.
ACTION: Notice of availability.

SUMMARY: In accordance with 37 CFR 404.7(a)(1)(i), announcement is made of the availability of U.S. Patent 5,246,862 for licensing. This patent has been assigned to the United States of America as represented by the Secretary of the Army, Washington, D.C.

ADDRESSES: United States Army Corps of Engineers, Waterways Experiment Station, ATTN: CEWES–CT–C, Vickskburg, MS 39180–6199.

FOR FURTHER INFORMATION CONTACT: Ms. Ruth C. Little (601) 634–2420.

SUPPLEMENTARY INFORMATION: The patent covers a method and apparatus for in-situ detection and determination of soil contaminants. The technique described involves dispensing a reagent carrying tape from the end of the penetrometer as the penetrometer is inserted into the soil. The tape is captured between the soil and the outer wall of the penetrometer. As the penetrometer moves with respect to the soil, the tape is pressed against an optical window in the penetrometer. Contaminants in the soil reacting with the reagents cause an optically sensible reaction in the tape to occur which is optically detected at the optical port of the penetrometer as the penetrometer moves with respect to the tape and the surrounding soil. The construction of the tape allows the optically sensible reaction occurring in the tape to be isolated from the masking effects of the soil. The patent further describes a method of employing the apparatus. The apparatus described in the patent would be of use in the

detection and quantification of contaminants in soil at sites suspected of having undesirable materials in subsurface soils or soil pore water.

Under the authority of section 11(a)(2) of the Federal Technology Transfer Act of 1986 (Pub. L. 99–502) and section 207 of title 35, United States Code, the Department of the Army, Corps of Engineers, Waterways Experiment Station wishes to license the above United States patent in an exclusive, partially exclusive or nonexclusive manner to any party interested in using the technology described in the above mentioned patents. Each interested party is requested to submit a proposal for an exclusive, partially exclusive or nonexclusive license. The proposals for using this technology will be evaluated using the following criteria: royalty, technical capability, size of business, and development plan.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 94–20575 Filed 8–22–94; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

[CFDA No. 84.170]

Jacob K. Javits Fellowship Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1995

Purpose of Program: To award fellowships to eligible students of superior ability, selected on the basis of demonstrated achievement and exceptional promise to undertake graduate study leading to a doctoral degree or the Masters of Fine Arts (MFA) at accredited institutions of higher education in selected fields of the arts, humanities, or social sciences This program supports the National Education Goal that calls for adult Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Eligible Applicants: Eligibility is limited to students who at the time of application have no more than 30-semester hours or 45-quarter hours or equivalent of graduate credit. Eligibility for fellowships to pursue a doctoral degree or the Masters of Fine Arts (MFA) that will not lead to an academic career is limited to U.S. citizens, permanent residents of the U.S., persons in the process of becoming U.S. citizens or permanent residents, and permanent residents of the Trust Territories of the Pacific Islands. Eligibility for fellowships to pursue a doctoral or MFA degree that will lead to an academic career is limited to U.S. citizens.

Deadline for Transmittal of Applications: November 28, 1994.

Applications Available: August 31, 1994.

Estimated Available Funds: $1,980,000.

Estimated Range of Awards: The Secretary has determined that the maximum fellowship stipend for academic year 1995–1996 is $14,400, which is equal to the level of support that the National Science Foundation is providing for its graduate fellowships. The institutional payment for academic year 1994–1995 was $9,243. The Secretary will adjust the institutional payment for academic year 1995–1996 prior to the issuance of grant awards based on the Department of Labor's determination of the Consumer Price Index for 1994.

Estimated Average Size of the Awards: $23,000.

Estimated Number of Awards: 80–100 individual fellowships.

Supplementary Information: Sixty percent of new awards will be available for fellowships to eligible applicants who have earned no credit hours applicable to a graduate degree. The remaining forty percent of new awards will be available for fellowships to all otherwise eligible applicants. In each of these two categories, sixty percent of these new fellowships will be awarded to applicants in the humanities, twenty percent to applicants in the social sciences, and twenty percent in the arts.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Parts 74, 75 (except as provided in 34 CFR 650.3(b)), 77, 82, 85 and 86; and (b) The regulations for this program in 34 CFR Part 650.

For Applications or Information Contact: Audrey M. Smith, Jacob K. Javits Fellowship Program, U.S. Department of Education, 400 Maryland Avenue, SW, Portals C80, Washington, DC 20202–5329. Telephone: (202) 260–3574. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260–9950; or on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins and Press Release). However, the official application notice for a discretionary grant competition is the notice published in the **Federal Register**.

Program Authority: 20 U.S.C. 1134, 1134h–k.

Dated: August 17, 1994.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 94–20568 Filed 8–22–94; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2550–002]

N.E.W. Hydro, Incorporated; Wisconsin; Notice of Environmental Assessment Scoping

August 17, 1994.

On March 29, 1994, the Federal Energy Regulatory Commission (Commission) issued a notice indicating that staff is ready to conduct an environmental analysis (REA Notice) for the existing Weyauwega Hydroelectric Project (project), located on the Waupaca River, with its dam about 5.5 miles upstream from the confluence of the Waupaca and Wolf Rivers, in Waupaca County, Wisconsin. The REA Notice also requested comments from Federal, state, and local resource agencies, licensees and developers, and any other interested groups (parties). Parties were given until May 29, 1994, to file comments.

The purpose of this notice is to advise all parties of the proposed scope of the staff's environmental analysis and to seek additional information pertinent to this analysis. The scope of analysis as presented herein is based on the information filed with the Commission by N.E.W. Hydro, Incorporated (the Applicant), comments received from the parties thus far, and the staff's independent analysis.

Proposed Action

The proposed action is to issue a minor license for the continued operation of the project. Project facilities consist of:

- an existing 240-foot-long dam comprised of (a) a 90-foot-long sheet pile faced earth section at the left abutment, (b) a 50-foot-long gated spillway section containing three 12-foot-wide by 10-foot-high Taintor gates

with a sill elevation of 760 feet National Geodetic Vertical Datum (NGVD), (c) a 29-foot-wide powerhouse, and (d) a 71-foot-long sheet pile faced earth section at the right abutment;

• an existing reservoir with a surface area approximately 250 acres, a gross capacity of approximately 1,259 acre-feet, and a normal pool elevation of 770.2 feet NGVD;

• an existing concrete and brick powerhouse measuring 56 feet by 29 feet in plan and containing a single turbine-generator unit rated at 400 kilowatts at a head of 12.3 feet and a hydraulic capacity of 507 cubic feet per second; and

• appurtenant equipment and facilities. No transmission line would be included among the project facilities.

The Applicant proposes the following measures relating to project operation to protect and enhance environmental resources in the project area.

• operate the project in a run-of-river mode;

• maintain the impoundment at a normal pool elevation of 770.2±0.25 feet NGVD;

• install staff gauges in the headpond and tailwater of the project;

• maintain an automatic water level sensor to monitor impoundment levels;

• maintain hourly log of project operations data; and

• determine the eligibility for listing on the National Register of Historic Places of the existing project facilities.

Project Alternatives

The Commission staff will consider alternatives, including enhancement measures not proposed by the Applicant. The staff will review and consider alternative recommendations for additional resource protection, or enhancement measures that may be appropriate to include in a license. Modifications could include recommendations by the agencies, the general public, and the staff.

Scope of the Environmental Assessment

Cumulative Effects

We have identified certain effects of continuing to operate the project—i.e., effects on water quality and flow regime in the Waupaca River, and those associated with facilitating upstream fish passage—that, when coupled with other activities on the Waupaca River, may affect environmental resources in a cumulative manner.

The geographic scope of cumulative effects analysis defines the physical limits or boundaries of the proposed action's effects on the resources. Since the proposed action affects the resources differently, the geographic scope for each resource may vary. In this case, for water quality and quantity, and fishery resources, the scope of analysis will encompass the mainstem of the Waupaca River. We chose this geographic scope for these resources because the effects of project operation are limited to this area and, in this case, these resources are directly and indirectly affected by project operations. Construction-related impacts are not an issue because no project-related construction is proposed.

For wildlife, cultural, recreational, and all other resources, we will focus our analysis on the project area as the appropriate geographic scope of analysis, unless persuaded by comments during the scoping process to do otherwise.

The temporal scope of our cumulative effects analysis includes a discussion of the past, present, and future actions and their effects on water quality and quantity, and fishery resources. Based on the license term, the temporal scope will look 30 to 50 years into the future, concentrating on the effects on the resource from reasonably foreseeable future actions. The historical discussion will, by necessity, be limited to the amount of available information for each resource. We've adequately identified the present resource conditions based on the license application and previous comments and will also document these in the environmental assessment (EA).

We are seeking further information from federal, state, and other agencies and non-government organizations (NGOs) pertaining to past, present, and future actions and effects on water quality and quantity, and fishery resources (in the form of previous studies, present plans, and future plans, goals or forecasts) in the Waupaca River.

Environmental Issues

The following items tentatively represent both site-specific and cumulative resource issues that would be examined in the EA. Issues that will also be emphasized in the cumulative effects analysis are designated by an asterisk (*).

Geology and Soils

• Beneficial effects of the proposed run-of-river operation over the existing mode of operation

• Potential erosion and sediment impacts resulting from canoe portage improvements

Water Quality and Quantity

• Project-specific and cumulative effects of project operations on water quality in the Waupaca River*

• Project-specific and cumulative effects of project operations on the flow regime in the Waupaca River*

Fishery Resources

• Effects of proposed project operations on the quantity and quality of aquatic habitat in the Waupaca River*

• Potential measures to ensure continuation of flow and protection of aquatic resources downstream of the projects in the event of flow interruption

• Impacts of reservoir fluctuations and reservoir drawdowns on near-shore aquatic habitat*

• Project-specific and cumulative impacts and benefits associated with facilitating upstream fish passage*

Terrestrial Resources

• Effect of current and proposed project operations on vegetation, wildlife, and associated habitat

• Effect of recreation facility construction and improvement on vegetation, wildlife and wildlife habitat

Threatened and Endangered Species

• Effect of current and proposed project operations on any federally-listed threatened or endangered species utilizing the project area

Cultural Resources

• Eligibility for listing on the National Register of Historic Places of the existing power facilities

• Effect of current and proposed project operations on properties that are eligible for listing on the National Register of Historic Places

Recreation

• Potential to enhance recreation opportunities by improving the canoe portage

Aesthetics

• Effects on impoundment shoreline and river reach downstream from powerhouse due to proposed changes in project operation

The EA will assess the project-specific effects on the above resources and whether these effects contribute adversely or beneficially to the affected environment.

EA Preparation Schedule

The preliminary schedule for preparing the EA for the Weyauwega Project is:

Milestones	Target date
Scoping	August 1994.
Draft EA	October 1994.
Final EA	December 1994.

Request for Comments

The Commission's scoping objectives are to:

- identify significant environmental issues,
- determine the depth of analysis appropriate to each issue,
- identify the resource issues not requiring detailed analysis, and
- identify reasonable project alternatives.

Federal, state, and local resource agencies, licensees and developers, Indian tribes, NGOs, other interested groups, and the general public are requested to file with the Commission information that they believe will assist the Commission staff in conducting an accurate and thorough analysis of the cumulative environmental effects of the proposed licensing of the Weyauwega Project being analyzed in this EA. The types of information sought include:

- information, quantified data, or professional opinion that may contribute to defining the geographical and temporal scope of the analysis and identifying significant environmental issues;
- identification of, and information from, any other EA, environmental impact statement, or similar document or study (previous, on-going, or planned) relevant to the proposed licensing activity on the Waupaca River;
- existing information and any data that would assist in describing the past and present actions and effects of the project and other developmental activities on water quality and quantity, and fishery resources (for example, fish stocking/management histories of the Waupaca River, historic water quality data and the reasons for improvement or degradation of the quality, locations of wastewater treatment outfalls or water intakes, or proposals to develop land and water resources within the river);
- identification of any Federal, state, or local resource plans and future project proposals that encompass the Waupaca River, with information on when the plans would be implemented, if known (for example, proposals to construct or operate water treatment facilities, recreation areas, water diversions, or implement fishery management programs); and
- documentation that would support a conclusion that the proposed project *does* or *does not* contribute to cumulative adverse or beneficial effects on resources and, therefore, should be excluded from further study or included for further consideration of cumulative effects. Documentation should include, but not be limited to, how the project interacts with other projects on the river and other developmental activities, results from studies, resource management policies, and reports from Federal, state, and local agencies.

To be useful in preparing the EA, the requested information must be filed with the Commission no later than 30 days past the date of this notice. Address all communications to:

Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426

All filings must clearly show at the top of the first page "Weyauwega Project, FERC No. 2550."

When filing scoping comments, you should submit an original and 8 copies; this will assure that the staff receives your information. Parties to the proceedings (as identified on the official Service List for the Weyauwega Project) must also send copies of their filings, and all attachments, to the other parties listed on the official Service List. The official Service List is available from the Secretary of the Commission at the same address above.

Any questions concerning the scoping process should be directed to Mary Golato (202–219–2804) or James T. Griffin (202–219–2799) at the Federal Energy Regulatory Commission, Office of Hydropower Licensing (HL–20.1), 810 First Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 94–20620 Filed 8–22–94; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. DI94–5–000]

Notice of Application

July 29, 1994.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Type of Application: Declaration of Intention.

b. Docket No.: DI94–5–000.

c. Date Filed: 07/21/94.

d. Applicant: Mr. Cameron Sharpe, P.O. Box 59, Sultan, WA 98294–0059, (206) 793–1722.

e. Name of Project: Colton Creek Camp.

f. Location: On Colton Creek and the North Fork Skykomish River, in Snohomish County, Washington, affecting lands of the United States within the Snoqualmie National Forest (T. 28 N., R. 11 E., secs. 24 and 25).

g. Filed Pursuant to: Section 23(b) of the Federal Power Act, 16 U.S.C. § 817(b).

h. Applicant Contact: Mr. Roger M. Benjamin, P.O. Box 1002, Monroe, WA 98272, (206) 794–5928.

i. FERC Contact: Diane M. Murray, (202) 219–2682.

j. Comment Date: September 16, 1994.

k. Description of Project: The proposed project consists of: (1) An intake; (2) a 1,200-foot-long pipeline; (3) a 70-kilowatt induction generator; (4) a transmission line; and (5) appurtenant facilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. Purpose of Project: The power will be used for heating and lighting of the Colton Creek Camp.

m. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTESTS", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named

documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of any agency's must also be sent to the Applicant's representative.

Lois D. Cashell,

Secretary.

[FR Doc. 94–20631 Filed 8–22–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–716–000]

Florida Gas Transmission Company; Request Under Blanket Authorization

August 17, 1994.

Take notice that on August 15, 1994, Florida Gas Transmission Company (FGT), 1400 Smith Street, Houston, Texas 77002, filed in Docket No. CP94–716–000 a request pursuant to Section 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to construct and operate a new meter station and to reassign natural gas delivery volumes for Peoples Gas System, Inc. (Peoples) in Pasco County, Florida, under FGT's blanket certificate issued in Docket No. CP82–553–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

FGT proposes to construct and operate a new meter station on its 30-inch West Leg pipeline in Pasco County, Florida to serve as a delivery point to Peoples in two existing transportation services under FGT's Rate Schedules FTS–1 and PTS–1. FGT also proposes to reassign certain gas volumes delivered from the Eustis Division to a newly created West Pasco Division. FGT states that the reassignment of the natural gas volumes to be delivered at the new meter station would not increase FGT's contractual gas deliveries to Peoples under the existing Rate Schedules FTS–1 and PTS–1 and would have no impact on FTS's peak day and annual deliveries.

FGT further states that its existing tariff does not prohibit the addition of the new meter station and that it has sufficient capacity to provide for the proposed deliveries without any detriment or disadvantage to its existing customers. FGT indicates that Peoples would reimburse FGT the costs for the construction of the new meter station which is estimated to be $151,000.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 94–20587 Filed 8–22–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–93–000]

KN Interstate Gas Transmission Company; Informal Settlement Conference

August 17, 1994.

Take notice that an informal settlement conference will be convened in this proceeding on Tuesday, August 30, 1994, at 10:00 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington, D.C., for the purpose of discussing settlement in the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant, as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervener status prior to the Commission's regulations (18 CFR 385.214).

For additional information, contact Lorna J. Hadlock at (202) 208–0737 or Donald Williams at (202) 208–0743.

Lois D. Cashell,

Secretary.

[FR Doc. 94–20588 Filed 8–22–94; 8:45 am]

BILLING CODE 6717–01–M

Notice of Cases Filed With the Office of Hearings and Appeals

Week of June 10 through June 17, 1994

During the Week of June 10 through June 17, 1994, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 C.F.R. Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall Be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585. Dated: August 16, 1994.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of June 10 through June 17, 1994]

Date	Name and location of applicant	Case no.	Type of submission
6/13/94	David W. Loveless, Idaho Falls, ID	LFA–0390	Appeal of an Information Request Denial. *If granted:* The May 9, 1994 Freedom of Information Request Denial issued by the Idaho Operations Office would be rescinded, and Mr. David W. Loveless would receive access to a complete report pertaining to contract DE-ACO1–84ID12721 with MK-Ferguson.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of June 10 through June 17, 1994]

Date	Name and location of applicant	Case no.	Type of submission
6/13/94	The Independent Oil Corporation, Milan, IL	LEE–0122	Exception to the Reporting Requirements. *If granted:* The Independent Oil Corporation would not be relieved of the requirements to prepare and file Form EIA–782B with the DOE Energy Information Administration.
6/14/94	A. Victorian, Nottingham, NG8 3NT England.	LFA–0392	Appeal of an Information Request Denial. *If granted:* The May 24, 1994 Freedom of Information Request Denial issued by the Office of Intergovernmental and External Affairs would be rescinded, and A. Victorian would receive access to the documents pertaining to the DOE/DOD MOU program on non-lethal weapons.
6/14/94	Standard Construction Company, Los Angeles, CA.	RR272–132	Request for Modification/Rescission in the Crude Oil Refund. *If granted:* The December 31, 1991 Dismissal Letter (Case No. RF272–37241) issued to Standard Construction Company regarding the firm's application for refund submitted in the Crude Oil refund proceeding would be modified.
6/14/94	U.S. West Communications Federal Services, Inc., Englewood, CO.	LFA–0391	Appeal of an Information Request Denial. *If granted:* The May 17, 1994 Freedom of Information Request Denial issued by the Albuquerque Operations would be rescinded, and U.S. West Communications Federal Service, Inc. would receive access to the Statement of Work and Price Schedule Sections of the bidder for Sandia National Laboratories/New Mexico's (SNL/NM) Request for Proposal #AF–8318.
6/17/94	Brindley Oil Company, St. Paul, MN	LEE–0123	Exception to the Reporting Requirements. *If granted:* The Brindley Oil Company would be relieved of the requirement to prepare and file Form EIA–782B with the DOE Energy Information Administration.
6/17/94	El Paso Natural Gas Company, Los Angeles, CA.	RR272–133	Request for Modification/Rescission in the Crude Oil Refund Proceeding. *If granted:* The March 13, 1991 Dismissal Letter (Case No. RF272–33414) issued to El Paso Natural Gas Company regarding the firm's crude oil refund application would be modified.
6/17/94	James W. Scott, Jr., Norfolk, VA	LFA–0393	Appeal of an Information Request Denial. *If granted:* James W. Scott, Jr. would receive access to documents concerning Robert Sherwood Scott at U.S. Government facilities in and around Oak Ridge, Tennessee, between August 1, 1945 and July 31, 1946.
6/17/94	Pro Fuels, Inc., Chadds Ford, PA	LEE–0124	Exception to the Reporting Requirements. *If granted:* PRO Fuels, Inc. would not be required to prepare and file Forms EIA–782B (Resellers'/Retailers' Monthly Petroleum Product Sales Report) and EIA–821 (Annual Fuel Oil and Kerosene Sales Report) with the DOE Energy Information Administration.
6/17/94	Terminix International Company, L.P., Los Angeles, CA.	RR272–134	Request for Modification/Rescission in the Crude Oil Refund Proceeding. *If granted:* The April 7, 1992 Dismissal Letter (Case No. RF272–59582) issued to Terminix Internatiional Company, L.P. regarding the firm's application for refund submitted in the Crude Oil Refund Proceeding would be modified.
6/17/94	Texaco/Canterberry Texaco, Hanford, CA	RR321–158	Request for Modification/Rescission in the Texaco Refund Proceeding. *If granted:* The April 25, 1990 and June 11, 1992 Dismissal Letters (Case Nos RF321–2203 and RF321–5775) issued to Canterberry Texaco regarding the firm's applications for refund submitted in the Texaco refund proceeding would be modified.
6/20/94	Terra Industries, Inc., Los Angeles, CA	RR272–135	Request for Modification/Rescission in the Crude Oil Refund Proceeding. *If granted:* The December 9, 1991 Dismissal Letter (Case No. RF272–25445) issued to Terra Industries, Inc. regarding the firm's application for refund submitted in the Crude Oil refund proceeding would be modified.

REFUND APPLICATIONS RECEIVED

Date received	Name of refund proceeding/name of refund applicant	Case No.
6/13/94	U.S. Air, Inc	RF344–11
6/13/94	U.S. Air, Inc	RF344–12

REFUND APPLICATIONS RECEIVED—Continued

Date received	Name of refund proceeding/name of refund applicant	Case No.
6/13/94	U.S. Air, Inc	RF344–13
6/14/94	Richard Neal Texaco	RF321–21003
6/14/94	Annel Tow Car, Inc	RF321–21002
6/14/94	Mel Schwartz	RF349–9
6/14/94	Oasis Truck Stop	RF349–10
6/14/94	Alfaro 66	RF349–11
6/14/94	Mel Schwartz	RF349–12
6/16/94	United Parcel Serv. of America	RF344–14
6/16/94	Sunland Refining Corporation	RF345–27
6/17/94	Elliott Bell, Inc	RF321–21004
6/17/94	Loop's Airport Texaco	RF321–21005
6/17/94	Energy Sales, Inc	RF321–21006
6/17/94	Koch Hydrocarbon Company	RF352–2
6/17/94	Air Canada	RF344–15
6/17/94	Alaska Airlines, Inc	RF344–17

[FR Doc. 94–20693 Filed 8–22–94; 8:45 am]
BILLING CODE 6450–01–P

Issuance of Decisions and Orders; Week of May 9 through May 13, 1994

Office of Hearings and Appeals

During the week of May 9 through May 13, 1994 the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeal

Morrison & Foerster, 5/12/94 LFA–0366

Morrison & Foerster filed an Appeal from a partial denial by the DOE of a Request for Information which the firm had submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that the FOIA Exemption 6 was properly invoked to withhold the names of test subjects of human radiation experiments. In reaching this conclusion, the DOE found that: (i) there is a significant privacy interest in the identity of individuals, (ii) there is little or no public interest in knowing the names of the test subjects, (iii) the death of test subjects does not extinguish all privacy interests in their identities. The Appeal was therefore denied.

Requests for Exception

Ed F. Hodges, Inc., 5/10/94 LEE–0056

Ed F. Hodges, Inc., (Hodges) filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship as a result of the filing requirement and, on March 30, 1994, issued a Proposed Decision and Order determining that the exception request should be denied. No Notice of Objection to the Proposed Decision and Order was filed at the Office of Hearings and Appeals of the DOE within the prescribed time period. Therefore, the DOE issued a final Decision and Order, denying Hodges' Application for Exception.

Refund Applications

Atlantic Richfield Company/B&P Motor Express, Inc. , 5/11/94 RR304–67

LK, Inc. (LK) filed a Motion for Reconsideration of a Decision and Order that denied its Application for Refund in the Arco refund proceeding with respect to purchases made by B & P Motor Express, Inc. (B & P), a bankrupt firm. In considering the motion, the DOE determined that LK did not present any compelling reason to reconsider the earlier decision. Specifically, the DOE found that the assignment of B & P's right to a refund to LK in the course of the bankruptcy proceeding did not expressly convey the right to apply for a product refund in the Arco proceeding. The DOE further found that the contract—in this case the assignment—specified what was to be included for consideration; therefore, all things not so specified should be excluded. Accordingly, LK's motion was denied.

Texaco Inc./Capitol Oil Company, 5/12/94 RF321–16898

The DOE issued a Decision and Order concerning an Application for Refund filed by Capitol Oil Company (Capitol) in the Texaco Inc. Subpart V special refund proceeding. The application claimed that Capitol was injured by Texaco's alleged violations of both the price and allocation regulations in effect during the consent order period. Capitol was granted a refund of $53,048 plus interest based on an allocation supply shortfall of 1,426,268 gallons of motor gasoline that Texaco wrongfully failed to supply Capitol and that Capitol was unable to replace with purchases from other suppliers. This refund was calculated using Capitol's gross profit margins during the period of the supply shortfall. The allocation portion of the refund was prorated to reflect the fact that the Texaco consent order is a negotiated compromise of the issues and liability involved in the enforcement proceedings against Texaco. Capitol also received a refund of $10,000 plus interest for its purchases of 10,786,009 gallons of refined petroleum products from Texaco based on the mid-range presumption of injury for pricing violation claimants. Therefore, the total refund granted to Capitol for both its allocation and price claims is $87,927, representing $63,048 principal plus $24,879 interest.

Lorenz Petroleum, Inc., 5/11/94 LEE–0092

Lorenz Petroleum, Inc. (Lorenz) filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering the request, the DOE found that the firm was suffering a gross inequity because of the medical condition of the owner. Accordingly, on March 21, 1994, the DOE issued a Proposed Decision and Order determining that the exception request should be granted in part and that Lorenz should be exempt from filing Form EIA–782B for two years. Since a Notice of Objection was not filed, this Decision and Order was issued in final form.

New Dixie Oil Corporation, 5/10/94 LEE–0074

New Dixie Oil Corporation (New Dixie) filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." The DOE determined that New Dixie did not meet the standards for exception relief because it was not experiencing a serious hardship or gross inequity as a result of the reporting requirements. Accordingly, exception relief was denied.

Paul Fisher Oil Co., Inc., 5/11/94 LEE–0091

Paul Fisher Oil Co., Inc. (Fisher) filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, the "Reseller/Retailers' Monthly Petroleum Product Sales Report." In considering the request, the DOE found that Fisher was not experiencing a serious hardship or gross inequity as a result of the reporting requirements. Accordingly, exception relief was denied.

R.V. Ratts Inc., 5/10/94 LEE–0082

R.V. Ratts, Inc. filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–23, the "Annual Survey of Domestic Oil and Gas Reserves." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship. Accordingly, exception relief was denied.

Winn's Gas & Oil, 5/10/94 LEE–0078

Winn's Gas & Oil filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship. On March 24, 1994, the DOE issued a Proposed Decision and Order determining that the exeption request should be denied. No Notice of Objection to the Proposed Decision and Order was filed at the Office of Hearings and Appels of the DOE within the prescribed time period. Therefore, the DOE issued the Proposed Decision and Order in final form.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals

Acetylene Supply Company	RF272–85852	05/11/94
Atlantic Richfield Company/Leon's Arco	RF304–14595	05/11/94
Atlantic Richfield Company/Zan's Arco et al	RF304–15015	05/12/94
Beacon Oil Company/Baker's Service	RF238–152	05/10/94
Beacon Oil Company/Rick French et al	RF238–96	05/10/94
Beacon Oil Company/Valley Oil Distributing Co	RR238–5	05/10/94
Commercial Electric Motors, Inc. et al	RF272–94411	05/12/94
Gulf Oil Corp./Jaxon Petroleum, Ltd	RF300–14652	05/10/94
Gulf Oil Corp./Lar-Lin, Inc	RF300–20459	05/09/94
Gulf Oil Corp./Stillwater Associates	RF300–18641	05/12/94
Gulf Oil Corp./Wood Gulf et al	RF300–20720	05/09/94
Jensen Transport, Inc. et al	RF272–92104	05/12/94
Sonoco Products Company	RF272–66546	05/11/94
Texaco Inc./Bi-Rite Oil Company, Inc	RF321–18714	05/13/94
Pruitt Oil Company	RF321–20221	
Texaco Inc./Bryan Station Texaco et al	RF321–14274	05/13/94
Texaco Inc./Nix Nu-Way Texaco et al	RF321–7123	05/11/94
Texaco Inc./Oldham's Texaco	RF321–20945	05/13/94
Mayberry Texaco	RF321–20953	
Westside Texaco	RF321–20961	
Texaco Inc./Tom Lacaze Texaco	RF321–20975	05/10/94
Texaco Inc./Tom Lass	RF321–20984	05/13/94
Texaco Inc./Tom's Texaco	RR321–157	05/11/94
The Buffalo News et al	RF272–84691	05/12/94

Dismissals

The following submissions were dismissed:

Name	Case No.
Forrest County School Dist	RF272–95201
H and W Oil Co., Inc	LEE–0115
High Grade Beverage	RF272–95219
Ingram Ready Mix, Inc	RF272–95139
J.F. Tollison Fertilizer	RF272–95167
Jamison & Son Bus Co	RF272–95188
Johnny Bowen Gulf Station #2.	RF300–21711
Southern Cast Stone Co.	RF272–95215
William H. Payne	LFA–0374

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

Dated: August 17, 1994

George B. Breznay,

Director, Office of Hearings and Appeals

[FR Doc. 94–20694 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

Office of Hearings and Appeals

Issuance of Decisions and Orders; Week of June 6 through June 10, 1994

During the week of June 6 through June 10, 1994, the decisions and orders summarized below were issued with respect to applications for exception and other relief filed with the Office of

Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Requests for Exception

Farmers Co-Operative Company, 6/7/94, LEE–0077

Farmers Co-Operative Company (Farmers) filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Reseller/Retailer's Monthly Petroleum Product Sales Report." In considering Farmers' request, the DOE found that the firm was not suffering a gross inequity or serious harship. On March 24, 1994, the DOE issued a Proposed Decision and Order determining that the exception request should be denied. No Notice of Objection to the Proposed Decision and Order was filed with the Office of Hearings and Appeals of the DOE within the prescribed time period. Therefore, the DOE issued the Proposed Decision and Order in final form, denying Farmers' Application for Exception.

May-Slade Oil Co., 6/6/94, LEE–0097

May-Slade Oil Co. filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship. Accordingly, exception relief was denied.

Supplemental Order

David Ramirez, 6/8/94, LWX–0013

A Hearing Officer of the Office of Hearings and Appeals issued a Supplemental Order awarding $122,088 in back pay and reasonable costs and expenses (including attorney's fees) to David Ramirez, a subcontractor employee at Brookhaven National Laboratory (BWL). The award supplements an Initial Agency Decision that found that BNL violated the Department's contractor employee protection regulations by directing the termination of Ramirez' employment in reprisal for his making protected safety disclosures. The Order denied Ramirez' request for compensation for damages resulting from the premature withdrawal of union pension and supplemental unemployment benefits, but, following the "collateral source rule," did not offset lost wages by the amount of state unemployment benefits. The award is not final since BNL has requested that the Secretary or her designee review the Initial Agency Decision.

Refund Application

Texaco Inc. Allgood Texaco Service et al., 6/6/94 RF321–749 et al.

The DOE issued a Decision and Order in the Texaco Inc. refund proceeding concerning eight Applications for Refund filed by Texaco retail outlets. One of these outlets did not have data showing its Texaco purchases, but did have evidence of the monthly amount of its cost of gasoline. The DOE estimated the firm's purchases for each month by dividing its monthly cost by an average cost for gasoline in that locality for that month. This average cost per gallon was calculated by adding to the dealer tank-wagon prices for regular gasoline as reported in Platt's Oil Price Handbook, the amount of state and federal gasolilne taxes and an amount to reflect the fact that the applicant's purchases included premimum and unleaded as well as regular gasoline.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Atlantic Richfield Company/Whaley's Arco	RF304–12092	06/07/94
Whaley's Arco #2	RF304–15457	
Whaley's Gulf	RF300–21763	
Clark Oil & Refining Corp./Plymouth Oil, Inc.	RF342–4	06/10/94
Covil Insulating Co.	RC272–231	06/09/94
Cross Street Service Companies Inc.	RF272–94078	06/07/94
Dysart-Geneseo Community Schools et al	RF272–88805	06/06/94
Gulf Oil Corporation/Bob's Gulf	RF300–21772	06/09/94
Gulf Oil Corporation/Danny R. Holton	RR300–257	06/07/94
Gulf Oil Corporation/J.R. Ridge Contractor & Co. et al	RF300–21355	06/09/94
Gulf Oil Corporation/Mackno Fuel Co., Inc.	RR300–191	06/07/94
T.E. Hinson Gulf	RR300–194	
Pangles Store	RR300–224	
Lincoln Mutual Service, Inc. No. 1	RF272–69006	06/10/94
Ralls County, Missouri et al	RF272–85137	06/10/94
Robert R. Wisdom Oil Co., Inc.	RF272–78256	06/10/94
State Mutual Life Assurance Co. of America et al	RF272–92207	06/10/94
Tempe Elementary Schools et al	RF272–87056	06/07/94
Texaco Inc./Ronnie's Wolf Road Texaco et al	RF321–19083	06/08/94
Young's Industries, Inc. et al	RF272–93500	06/09/94

Dismissals

The following submissions were dismissed:

Name	Case No.
Arcadia Valley R–II School District.	RF272–80005
Brentwood Texaco	RF321–5969
Circle City Texaco	RF321–8186
City Texaco	RF321–12112
Darris Texaco Service	RF321–19155
DE Goodrich	LFA–0370
Finney's Texaco	RF321–15931
Glo Distributing, Inc	RF321–19852
Jodie's Texaco	RF321–6608
Keci Corporation	LFA–0385
Keci Corporation	LFA–0386
Koppers Co., Inc.	RF321–20056
L. Hardy Co.	RF321–6512
Lawrence County Board of Education.	RF272–92281
Moss Midway Texaco	RF321–12104
Park Ridge Garage, Inc.	RF321–6773
Putnam County	RF272–85628
Richins Texaco Service	RF321–15885
Thurston Aviation, Inc.	RF272–92216
Town of Hamilton	RF272–85458

Name	Case No.
Wallace Texaco	RF321–6646
Wayne M. Cooper	LFA–0380
Woodstock Texaco	RF321–174

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

Dated: August 16, 1994

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 94–20698 Filed 8–22–94 8:45 am]

BILLING CODE 6450–01–P

Notice of Issuance of Decisions and Orders by the Office of Hearings and Appeals

Week of April 25 through April 29, 1994

During the week of April 25 through April 29, 1994 the decisions and orders summarized below were issued with respect to applications for refund or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Refund Applications

J.I. Case, 4/28/94, *RF272–91769*

The DOE issued a Decision and Order concerning an Application for Refund filed in the crude oil refund proceeding by J.I. Case. The Application was based upon purchases of petroleum products made by the agricultural department of International Harvester. J.I. Case had acquired the agricultural department of International Harvester in 1985. However, the parent firm of J.I. Case, Tenneco, had applied for and received a refund from the Refiners Escrow account in the Stripper Well proceeding. Upon receiving that refund, Tenneco was required to execute a "Release of Claims" that waived its right and the rights of any of its affiliates or subsidiaries (such as J.I. Case) to receive a refund in the crude oil refund proceeding. Accordingly, the DOE denied the J.I. Case Application.

Osceola Electric Cooperative, Inc., 4/29/94, *RF272–91868*

The DOE issued a Decision and Order concerning an Application for Refund filed by Osceola Electric Co-op in the DOE crude oil refund proceeding. Previously, Osceola County Cooperative Oil Co.—of which Osceola Electric is a member—had received a refund in the crude oil proceeding based upon its total purchases of petroleum products. These purchases included those sold to members; therefore, the Osceola Electric Co-op Application was denied.

Texaco Inc./Dees Petroleum Products, 4/28/94, *RR321–151*

The DOE issued a Decision and Order in response to a Motion for Reconsideration filed by Dees Petroleum Products (Dees) in the Texaco Inc. special refund proceeding. The Motion concerned a May 18, 1992 denial of the portion of Dee's original refund application based on Texaco's alleged failure to supply petroleum products for Dees' resale to sixty-three motor gasoline retailers. The basis for the denial was the finding that Dees was not the designated supplier of those retail outlets. Dees requested reconsideration of that finding and advanced the new claim that it had been disproportionately overcharged in its purchases from Texaco. The DOE found that the material Dees submitted presented no basis for reconsideration of the May 18, 1992 Decision and Order; the Motion for Reconsideration was accordingly denied.

Texaco, Inc./Horton's Texaco Service, 4/28/94, *RR321–142*

The DOE issued a Decision and Order concerning a Motion for Reconsideration filed in the Texaco Inc. special refund proceeding by D.C. Horton, owner of Horton's Texaco Service. Horton sought to have the OHA reconsider a decision dismissing a prior refund request because necessary requested supporting information had not been supplied. Horton stated that he had responded to the OHA information request in a timely manner; Aikin Energy, Inc., the "filing service" that had represented him, had failed to promptly forward the data. Based upon the past lackluster performance of Horton's filing service, DOE determined that Horton's claim was credible, and granted a direct refund of $3,162.

Texaco Inc./Rollins Texaco, et al., 4/25/94, *RF321–19205, et al.*

Applications for Refund were filed by Wilson, Keller and Associates on behalf of five former Texaco retailers that were unable to locate records sufficient to prepare monthly schedules of their purchases of Texaco motor gasoline. The Applications were based on estimated purchase volumes developed by Wilson, Keller and Associates that were based upon the applicants' tax returns and data from the "Monthly Gallonage of Gas Stations/National Petroleum News 1973–1981." In considering these claims, the DOE found that the estimates were reasonable in most cases. However, when the Wilson Keller methodology appeared to produce unreasonable results, the DOE used a different estimation technique. Accordingly, the DOE issued a Decision and Order granting the Applications in part.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Central Louisiana Electric Co., Inc. et al	RF272–92709	04/28/94
City School District of Batavia et al	RF272–86679	04/25/94
Decatur County Public Works et al	RF272–93100	04/28/94
Gulf Oil Corp./Acadia Fuel & Oil Distributors et al	RF300–20674	04/29/94
Gulf Oil Corp./BRW Fuel Company	RF300–21789	04/26/94
Gulf Oil Corp./Lampton-Love, Inc	RF300–18025	04/25/94
Gulf Oil Corp./MacArthur Petroleum & Solvent Co. et al	RF300–8420	04/29/94
Gulf Oil Corp./Mount Holly Ice & Fuel Co	RF300–18324	04/28/94
D&L Grocery	RF300–18767	
Gulf Oil Corp./Taylor Gulf Service	RF300–16006	04/26/94
Gulf Oil Corp./Village One Stop #2 et al	RF300–15595	04/29/94
Heard County, Georgia et al	RF272–85202	04/25/94
Jess Radle Son, Inc	RF272–93116	04/28/94

Martin County et al	RF272–87667	04/26/94
Meriden-Cleghorn Community School District et al	RF272–79149	04/29/94
NL Industries, Inc. d/b/a Baroid Corporation	RF272–14948	04/28/94
NL Industries, Inc. d/b/a Baroid Corporation	RD272–14948	
Rogers Cartage Co. et al	RF272–80169	04/28/94
Shell Oil Company/Fullerton Pulaski Shell	RF315–4840	04/28/94
Texaco Inc./Hillmer's Texaco Service et al	RF321–11275	04/29/94
Texaco Inc./Lloyd's Texaco Service #1 et al	RF321–11271	04/28/94
W.J. Terry & Sons, Inc	RF272–85961	04/26/94

Dismissals

The following submissions were dismissed:

Name	Case No.
Bonduel School District	RF272–80498
Dalco Petroleum Company	RF340–76
Johnny Isbell Texaco	RF321–12184
Lajet, Inc	RF340–151
Moundridge Unified School District 423.	RF272–80129
Paul Gavornik Service	RF321–17990
R.B. Nutt's Texaco	RF321–10899
Robinwood Texaco	RF321–4670
Sunnyland Packing Co	RF272–93000
Super 90 Texaco Service Station.	RF321–10834
Woodstock Grismill Companies, Inc.	LEE–0111

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

Dated: August 16, 1994.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 94–20699 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

Issuance of Proposed Decisions and Orders by the Week of July 25 Through July 29, 1994

During the week of July 25 through July 29, 1994 the proposed decisions and orders summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to applications for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these proposed decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays.

Dated: August 17, 1994.

George B. Breznay,

Director, Office of Hearings and Appeals.

Berreth Oil Inc., Mishawaka, in, LEE–0093 Reporting Requirements

Berreth Oil Inc., (Berreth) filed an Application for Exception from the provision of filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report" and Form EIA–821, entitled "Annual Fuel Oil and Kerosene Sales Report." The Exception request, if granted, would permit Berreth to be exempted from filing Forms EIA–782B and EIA–821. On July 25, 1994, the Department of Energy issued a Proposed Decision and Order which determined that the Exception request be denied.

The Outpost Station/Outpost Country Store Phelan, CA, LEE–00120, Reporting Requirements

The Outpost Station/Outpost Country Store filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship. Accordingly, on July 27, 1994, the DOE issued a Proposed Decision and Order determining that the exception request should be denied.

Texpar Energy, Inc., Waukesha, WI, LEE–0119, Reporting Requirements

Texpar Energy, Inc. (Texpar), filed an Application for Exception from the provision of filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." The exception request, if granted, would permit Texpar to be exempted from filing Form EIA–782B. On July 27, 1994, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

[FR Doc. 94–20695 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

Issuance of Decisions and Orders Week of May 30 through June 3, 1994

During the week of May 30 through June 3, 1994, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

Concord Oil Company, 6/1/94, LFA–0372

Concord Oil Company (Concord) filed an Appeal from a determination issued by the Albuquerque Operations Office

(Albuquerque) in response to a request from Concord under the Freedom of Information Act. Concord sought various contracts pertaining to work already performed or to be performed on a Uranium Mill Tailing Remedial Action (UMTRA) project. In considering the Appeal, the Office of Hearings and Appeals found that an attachment to a subcontract between MK-Fergusen (MK-F) and the DOE was not an agency record subject to the FOIA and that Exemption 4 of the FOIA permitted the withholding of a section detailing personnel and salary information of a MK-F contract. Accordingly, the Appeal was denied.

Shannon & Wilson, Inc., 6/1/94, LFA–0371

Shannon & Wilson, Inc. filed an Appeal from a partial denial by the Richland Operations Office of a Request for Information which it had submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that some of the information that had initially been withheld under Exemption 5 should have been released to the public. The DOE found that a more selective redaction would allow additional information to be released without revealing the identities of individuals. The DOE further found that this result was supported by a October 4, 1993 Memorandum for Heads of Departments and Agencies from Attorney General Janet Reno. In addition, DOE found that Richland had failed to conduct a public interest determination. However, the DOE also found that some of the information requested by the Appellant could have been withheld under Exemptions 4 and 6. Accordingly, the Appeal was remanded to Richland for further processing.

Request for Exception

Midstream Fuel Service, Inc., 5/31/94, LEE–0083

Midstream Fuel Service, Inc. (Midstream), filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering the request, the DOE found that the firm was suffering a gross inequity due to the maternity leave of two of the firm's employees. Accordingly, the DOE determined that the exception request be granted in part and that Midstream should be granted an extension of time until May 1994 in which to file the forms due between February 1, 1994, and May 1, 1994.

Wortmann Oil Co., Inc., 6/3/94, LEE–0112

Wortmann Oil Company, Inc. (Wortmann), filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering the request, the DOE found that the firm was suffering a gross inequity due to the protracted illness of the firm's owner. Accordingly, the DOE determined that the exception request be granted and that Wortmann should be permanently removed from the survey.

Protective Order

Westinghouse Hanford Company, 6/2/94, LWJ–0004

Westinghouse Hanford Company (WHC) filed a request that the OHA issue a Protective Order concerning certain documents which the company agreed to provide to the Government Accountability Project (GAP) and Thad M. Guyer, counsel for Helen "Gail" Oglesbee, in connection with a hearing request filed by Oglesbee under the Department of Energy's Contractor Employee Protection Program, 10 C.F.R. Part 708. With its request, WHC submitted a Stipulated Protective Order to which WHC, GAP and Mr. Guyer agreed to be bound. The Order stated, *inter alia*, that GAP and Mr. Guyer shall not make use of nor disclose any information in the documents provided by WHC except for purposes related to the Part 708 proceeding, and that upon the termination of the proceeding shall either destroy the documents or return them to WHC. The Hearing Office reviewed the Stipulated Protective Order and concluded that it should be issued as an Order of the Department of Energy. Accordingly, the Order was issued pursuant to the authority given the Hearing Officer under the Part 708 regulations to "arrange * * * for the production of specific documents or other physical evidence, provided a showing of the necessity for such * * * evidence has been made to the satisfaction of the Hearing Officer." 10 C.F.R. § 708.9(e).

Implementation of Special Refund Procedures

N.C. Ginther Company, 5/31/94, LEF–0060

The DOE issued a Decision and Order implementing procedures for the distribution of $144,864.85, plus accrued interest, in alleged overcharges obtained from N.C. Ginther Company. These funds were remitted to settle possible pricing violations in the firm's sales of natural gas liquid (ngl) products during the period September 1, 1973 through March 31, 1977. The DOE determined that these funds will be distributed in accordance with the Petroleum Overcharge Distribution and Restitution Act of 1986. Accordingly, Applications for Refund will be accepted from any party who purchased ngl products from Ginther during the period, September 1, 1973 through March 31, 1977. The specific information to be included in Applications for Refund is included in the Decision.

Refund Applications

Sauvage Gas Co./Wynn Horney, 6/3/94, RF308–10

The DOE issued a Decision and Order granting an application filed by Wynn Horney, a former owner of Springs Gas Service, Inc. (Springs), in the (Sauvage) special refund proceeding. Springs was a reseller of Sauvage petroleum products during the consent order period. Mr. Horney and Sauvage each owned 50% of Springs. However, the OHA found that Springs was operationally distinct from Sauvage and did not consider Mr. Horney and Sauvage to be a single firm. The OHA found that Mr. Horney alone would have borne all injury stemming from Sauvage's alleged price overcharges. Thus, although he was only a 50% owner of Springs, Wynn Horney was eligible to receive 100% of any refund awarded on behalf of Springs. Mr. Horney submitted a detailed demonstration of injury and requested a full volumetric refund based upon Springs' purchases of 7,091,186 gallons of Sauvage propane during the consent order period. Springs' data indicated that the firm's cumulative banked costs were well in excess of the refund requested and the competitive disadvantage analysis submitted by Mr. Horney clearly indicated that Springs was injured in its purchases from Sauvage. Accordingly, the OHA found that the applicant's injury was of sufficient magnitude to justify an award of the entire volumetric allocation. Mr. Horney was granted a refund of $13,204 on behalf of Springs, to which was added $9,886 in interest for a total of $23,090. No further refunds to identifiable purchasers of Sauvage products await disbursement. Therefore all unclaimed funds remaining in the Sauvage escrow account were made available for indirect restitution pursuant to the Petroleum Overcharge Distribution and Restitution Act of 1986

contained in Title III of Pub. L. No. 99–509.

Texaco Inc./James E. Hovis Texaco, 6/2/94, RF321–20997

The DOE issued a Decision and Order partially rescinding an Application for Refund filed on behalf of James E. Hovis Texaco in the Texaco Inc. special refund proceeding. The DOE found that the applicant had been granted a refund for the entire refund period on the basis of a Texaco schedule of purchases for a location at which he was the operator for only a portion of the refund period (April 1976–January 1981). The DOE then received from Texaco a schedule of purchases that corresponded to a location where the applicant was the operator previous to being the operator at the location for which he was granted a refund (November 1973–April 1975). However, the second schedule of purchases showed fewer gallons of product delivered to the earlier location than the number of gallons for which James E. Hovis Texaco was erroneously granted. Therefore, the DOE rescinded the difference between the refund granted to James E. Hovis Texaco and the refund that should have been granted based upon correct gallonage information.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Atlantic Richfield Company/B&D Butane Company	RR304–68	06/01/94
Atlantic Richfield Company/Hord Oil, Inc.	RF304–13547	06/03/94
Dick Cowan's ARCO	RF304–13972	
Devoe & Raynolds Company	RF272–53573	06/03/94
E.M.H. of Larsen et al.	RF272–93819	06/02/94
Gulf Oil Corp./American Dusting Co., Inc. et al.	RF300–21315	05/31/94
Gulf Oil Corp./Coleman Oil Co., Inc.	RF300–5921	05/31/94
Oasis Gulf	RF300–21783	
T & G Oil Co.	RF300–21784	
Cline St. Gulf	RF300–21785	
Gulf Oil Corp./Griffith Oil Co., Inc.	RF300–19752	06/03/94
Gulf Oil Corp./Transport Oil Station #530	RF300–16195	06/03/94
Donald Harrison Gulf	RF300–16324	
Livermore Valley et al.	RF272–80004	06/02/94
Shell Oil Company/Salinas Valley Oil Company	RF315–10154	06/01/94
Texaco Inc./Boris Texaco Service et al.	RF321–14425	06/02/94
Texaco Inc./Garden Street Texaco et al.	RF321–17253	06/02/94
Texaco Inc./Highway Administration et al.	RF321–16892	06/02/94
Texaco Inc./Stuckey's Store # 171 et al.	RF321–16308	06/02/94
Transportation, Inc.	RF272–91664	06/01/94
Westplains Energy et al.	RF272–91555	06/02/94

Dismissals

The following submissions were dismissed:

Name	Case No.
Danny R. Holton	RR300–220
Franklin Texaco	RF321–6323
G. E. Plastics	RF272–91752
G. E. Plastics	RF272–91686
Jap Oil Company	LEE–0117
K–Tex Oil and Supply, Inc	RF321–14807
R&R Oil, Inc.	LEE–0107
South Mississippi Electric Association.	RF321–20041
Texfi Industries, Inc	RF272–78402
William H. Payne	LFA–0376

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

Dated: August 16, 1994.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 94–20696 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

Issuance of Decisions and Orders; Week of June 27 Through July 1, 1994

During the week of June 27 through July 1, 1994, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

John Gilmore, 6/29/94, LFA–0388

Mr. John Gilmore filed an Appeal from a denial by the Albuquerque Operations Office of a Request for Information which his attorney Lee Tien had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that the material requested computer source code of conferencing software developed by Sandia National Laboratories, was not considered agency records subject to disclosure under the FOIA. The DOE also concluded that even if the software could be considered records, the programs would likely be withheld under Exemption 4 because they are commercially valuable to Sandia Corporation, which sold two software licenses and expects to sell more. The Appeal was therefore denied. The important issue that was considered in the Decision and Order was whether computer programs could be considered agency records subject to disclosure under the FOIA.

Teresa Longstreet, 6/27/94, LFA–0389

Teresa Longstreet filed an Appeal from a denial by the Oak Ridge Operations Office (Oak Ridge) of a request for Information she had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that the search for responsive documents conducted by Oak Ridge was adequate. Accordingly, the DOE denied

Ms. Longstreet's Appeal. An important issue considered in the Decision and Order was the adequacy of the search.

Requests for Exception

Fitch Oil Company, Inc., 6/30/94, LEE–0101

Fitch Oil Company, Inc. (Fitch), filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Sales Report." In considering the request, the DOE found that the firm was suffering a gross inequity due to the firm's personnel shortage. Accordingly, the DOE determined that the exception request be granted in part and that Fitch be relieved of the reporting requirement from April 1994 through December 1994.

Saupe' Enterprises, Inc., 6/30/94, LEE–0105

Saupe' Enterprises, Inc. (Saupe') filed an Application for Exception from the provisions of the Energy Information Administration (EIA) reporting requirements in which the firm sought relief from filing Form EIA–782B, entitled "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering the request, the DOE found that the firm was not experiencing a serious hardship or gross inequity as a result of the reporting requirements. Accordingly, exception relief was denied.

Swan Oil Company, 6/29/94, LEE–0076

Swan Oil Company, filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Resellers'/Retailers' Monthly Petroleum Product Sales Report." In considering this request, the DOE found that the firm was not suffering a gross inequity or serious hardship. On March 29, 1994, the DOE issued a Proposed Decision and Order determining that the exception request should be denied. No Notice of Objections was filed. Consequently, the DOE issued the Proposed Decision and Order in final form, denying Swan Oil Company's Application for Exception.

Wells Oil Co., 6/30/94, LEE–108

Wells Oil Co. filed an Application for Exception from the provisions of the EIA reporting requirements in which the firm sought an exception from filing Form EIA–782B. In considering the request, the DOE found that the firm was not suffering a serious hardship or gross inequity as a result of the reporting requirements. Accordingly, exception relief was denied.

Refund Applications

Texaco Inc./Energy Sales, Inc., 6/29/94, RF321–20015; RF321–20074; RF321–21006

The DOE issued a Decision and Order in the Texaco Inc. refund proceeding concerning three Applications for Refund filed with respect to Texaco purchases made by Energy Sales, Inc. (ESI), a dissolved corporation. The DOE noted that generally where the corporation has been dissolved, the owners at the time of dissolution are usually entitled to the refund. There was no dispute that John Grisham owned 24.33 percent of ESI, and he was granted a refund equal to 24.33 percent of the refund due ESI. The other two applicants, David Montgomery and Clarence Stapp, both claimed the remaining 75.67 percent of ESI's refund. Montgomery claimed to have purchased ESI's corporate shares from Stapp in 1986, and he submitted a copy of the purchase contract to support his claim. Stapp claimed that the conditions of the contract were never fulfilled and that he retains the stock certificates. The DOE found the stock certificates were issued in Montgomery's name. Stapp retained custody of the certificates only to protect a security interest, and, he had never exercised a stock power that would have transferred them to his name. The DOE also noted that the loan for which the stock certificates constituted a security interest had been paid off. Under these circumstances, the DOE found that Montgomery was the owner of the stock. Accordingly, the refund application filed by Montgomery was granted and the application filed by Stapp was denied.

Texaco Inc./Lacey-Elliott Texaco, Elliott Bell, Inc., 6/29/94, RF321–19844

On June 18, 1991, the DOE issued a Decision and Order in the Texaco Inc. refund proceeding concerning an Application for Refund filed by Mrs. Earl Elliott on behalf of Elliott Bell, Inc., a Texaco jobber. That refund was based upon the applicant's claim that her husband operated the business. Subsequently, the children of Trammel Lacey filed an application for refund for the same business under the name Lacey-Elliott Texaco. They stated that Mr. Lacey and Mr. Elliott were partners for part of the refund period. In response, Mrs. Elliott claimed that her husband acquired all rights to the business, including the right to the Texaco refund, when he bought out Mr. Lacey's share.

The DOE noted that, generally, the owners of the firm at the time of the Texaco purchases are entitled to the refund. This right is not normally transferred to the purchaser of a partner's interest unless the interest was transferred under a contract that either specifies refunds as one of the assets being transferred or leaves no doubt that the parties intended the contract to transfer rights to refunds. The DOE found that Mr. Lacey had owned 40 percent of the business and that nothing in the contract indicated an intent to transfer rights to refunds. Accordingly, the DOE found that the children of Mr. Lacey should receive a refund based upon 40 percent of the firm's purchases for the portion of the refund period prior to Mr. Lacey's sale of the business to Mr. Elliott, and Mrs. Elliott should repay, with interest, that portion of the refund she had previously received that was attributable to Mr. Lacey's share of the business.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Conrad Coop et al	RF272–93754	06/29/94
Dahlman Truck Lines, Inc. et al	RF272–82513	06/30/94
Enron Corp./Fuel Products, Inc.	RF340–69	06/30/94
Taylor-Harbin L.P. Gas	RF340–133	
Domex, Inc.	RF340–191	
Gulf Oil Corporation/Braniff Airways, Inc.	RF300–20801	07/01/94
Gulf Oil Corporation/Dothan Aviation Corp., Inc. et al	RF300–15434	06/29/94
Gulf Oil Corporation/Enserch Corporation	RF300–20585	06/29/94
Gulf Oil Corporation/Hammond Country Store	RR300–186	06/29/94
McClure's Gulf	RR300–208	

Gulf Oil Corporation/Trenton Lehigh Coal & Oil Co. et al	RR300–78	06/29/94
Iuka Cooperative Exchange et al	RF272–88266	06/29/94
Setton Company, Inc.	RF272–94484	06/29/94
Town of Billerica Fire Dept.	RF272–94490	
Texaco Inc./Bellis Texaco et al	RF321–19332	06/27/94
Texaco Inc./Bobis Texaco et al	RF321–19742	06/30/94
Texaco Inc./Gold Medal Farms Inc. et al	RF321–6587	07/01/94
Texaco Inc./James River Corporation et al	RF321–19655	06/30/94
Texaco Inc./Joe's Texaco #1	RF321–20230	07/01/94
Joe's Texaco #2	RF321–20231	
Texaco Inc./Linwood Texaco et al	RF321–16861	06/30/94
Texaco Inc./Nora Texaco et al	RF321–415	06/29/94
Union County School District et al	RF272–82427	06/29/94
Warrden County, New York et al	RF272–85209	06/29/94

Dismissals

The following submissions were dismissed:

Name	Case No.
Air Vista Texaco	RF321–11304
Amax Copper, Inc	RF321–19926
Auburn Texaco	RF321–13877
Bagwell Service Station	RF272–95736
Bill Alsbury Texaco	RF321–20870
Bill's Texaco	RF321–19582
Dan's Texaco	RF321–16249
Holmes Oil Corporation	RF315–10186
Howard Bush's Texaco #2	RF321–10624
John Diramarian Texaco	RF321–20438
John Paul's Texaco	RF321–20684
Kennedy Realty Co	RF272–78323
Kinzeler Marine, Inc	RF321–19911
Mac's Triangle Service	RF321–12101
Middlesex Builders, Inc	RF272–77675
Miss Valley C U Dist 166	RF272–87093
Oakland C U School Dist 5	RF272–87140
Pats Fuel Oil	RF300–20050
Regency Texaco	RF321–20764
Salt Meadow Shell	RF315–8857
Strickland Texaco	LFA–7049
Styles Arco	RF272–95735
The Armrel-Byrnes Co	RF321–19922
Vic's Monterey	RF272–95747
Warrick Eastside Texaco	RF321–11214
Woodbridge Gardens Association.	RF272–78346
Woodbridge Village Association.	RF272–78354
Wyomissing Area School District.	RF272–81933

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, Room 1E–234, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: August 16, 1994.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 94–20697 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

Notice of an Amendment to the Environmental Impact Statement for the Interim Management of Nuclear Materials at the Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice.

SUMMARY: On March 17, 1994, the Department of Energy (DOE) published a Notice of Intent to prepare an Environmental Impact Statement (EIS) for the Interim Management of Nuclear Materials at the Savannah River Site (SRS) (59 FR 12588). One type of material to be analyzed in that EIS, nitrate solutions of plutonium in tanks in the F–Canyon chemical separations facility, has been shown to be capable of presenting a significant safety issue if left in its current condition and location. Accordingly, DOE has decided to prepare a separate EIS, on an urgent schedule, for the proposed stabilization of these F–Canyon plutonium solutions.

ADDRESSES: Please direct comments, suggestions, and questions concerning the F–Canyon Plutonium Solutions EIS project to: Dr. Karen Hooker, NEPA Compliance Officer, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, South Carolina 29802, (803) 725–3957 or (800) 242–8269.

Mark the envelopes: "F–Canyon Plutonium Solutions EIS."

For general information on DOE's NEPA process, please contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Oversight (EH–25), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: For background information on the SRS, and for a discussion of the underlying purpose and need for stabilizing nuclear materials at the SRS, please refer to the original March 17, 1994 Notice of Intent (59 FR 12588).

Since the publication of the Notice of Intent, DOE has determined that a potentially significant safety concern exists with plutonium solutions in the F–Canyon chemical separations facility. The condition of specific plutonium solutions in the F–Canyon chemical separations facility warrants consideration of their stabilization in advance of any decisions made subsequent to the completion of the Interim Management of Nuclear Materials EIS.

DOE will prepare an EIS on the F–Canyon Plutonium Solutions, pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended (42 USC 4321 *et seq.*). The EIS for the balance of the materials described in the Notice of Intent will retain the original title, "Interim Management of Nuclear Materials."

Approximately 85,000 gallons of in-process plutonium solutions currently are held in tanks in F–Canyon. Such plutonium solutions historically and routinely have been created and treated in the F–Canyon as in-process materials of SRS production and reprocessing programs. However, the solutions currently in storage have been held much longer than called for in the original design and routine operation of the Canyon. Furthermore, as a result of specific manipulations of the solutions' chemistry to maintain safety, the solutions are now in a condition not previously envisioned for routine operations. These safety-related alterations to solution chemistry have prevented an imminent hazard from occurring. However, the operations staff of F–Canyon has documented a slow deterioration in solution chemistry, which requires continuous vigilance to assure safe storage and to avoid potentially severe radiological impacts should an accident occur. Therefore, DOE proposes to evaluate alternatives for the immediate stabilization of these plutonium solutions.

The plutonium solutions in F–Canyon include mixtures of plutonium-239 and uranium-238, as well as simple

plutonium-239 solutions. Some of these solutions also contain fission products from irradiation in a nuclear reactor, as well as naturally occurring products from radioactive decay during storage. DOE proposes to stabilize these solutions by conversion of the plutonium in solution to a solid state as plutonium metal. However, because it is not needed for weapons, the chemical purity of the plutonium would be made sufficient only for stabilization and safe long-term storage, rather than in compliance with purity standards previously set for weapons materials. The entire conversion process would take place in existing facilities in the F–Canyon building.

Proposed Action

The Department proposes to stabilize the plutonium solutions currently within the F–Canyon facility using existing standard operating procedures and proven processing capabilities. Based on technical and management judgment, DOE believes that these plutonium solutions present a safety concern that warrants expeditious processing to a more stable and storable form while decisions are made regarding interim to long-term disposition of this plutonium. Based on current information, the preferred option would be to operate the F–Canyon and FB-Line facilities only as may be necessary for stabilization or to ensure the safe management of these plutonium solutions.

Alternatives Proposed for Consideration

DOE will identify and evaluate potential alternatives to the expedited stabilization or enhanced safe management of the F–Canyon plutonium solutions. Consistent with NEPA's requirement that the "no action" alternative be considered, DOE will evaluate the potential environmental impacts of continuing to manage the F–Canyon plutonium solutions in their current form until decisions regarding interim to long-term disposition are made.

Comments

Because the issues to be addressed in the F–Canyon Plutonium Solutions EIS were included within the Interim Management of Nuclear Materials EIS scoping process, no additional scoping meetings will be held. An Implementation Plan will be released shortly that identifies the comments received during the previously held public scoping process, including those issues related to the F–Canyon Plutonium Solutions EIS, and identifies those matters to be addressed in both EIS's. All comments received during the scoping process relevant to the stabilization of F–Canyon plutonium solutions will be addressed in the preparation of the F–Canyon Plutonium Solutions EIS.

DOE intends to complete the Draft F–Canyon Plutonium Solutions EIS in September 1994, and will announce its availability in the Federal Register. DOE will solicit comments from the public, organizations, and other agencies on the Draft EIS, and will consider all comments in its preparation of the Final EIS.

Related Publication

Copies of the report prepared by DOE as a result of its evaluation of the plutonium solutions in F–Canyon, *Assessment of Interim Storage of Plutonium Solutions in F–Canyon and Mark-31 Targets in L-Basin at Savannah River Site* (DOE EH–0397P, in two volumes) can be obtained from: Sharon A. Root, Manager, Nuclear Safety Information Center (EH–15), U.S. Department of Energy, Washington DC 20585, Phone: 301/903–8686, FAX: 301/903–9823.

Issued in Washington, DC, this 17th day of August, 1994.

Tara O'Toole,

Assistant Secretary, Environment, Safety, and Health.

[FR Doc. 94–20692 Filed 8–22–94; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5056–7]

Office of Research and Development; Ambient Air Monitoring Reference and Equivalent Methods; Receipt of Application for a Reference Method Determination

Notice is hereby given that on July 12, 1994, the Environmental Protection Agency received an application from Advanced Pollution Instrumentation, Inc., 8815 Production Avenue, San Diego, California 92121–2219, to determine if their Model 200A Nitrogen Oxides Analyzer should be designated by the Administrator of the EPA as a reference method under 40 CFR Part 53. If, after appropriate technical study, the Administrator determines that this method should be so designated, notice thereof will be given in a subsequent issue of the Federal Register.

Carl Gerber,

Acting Assistant Administrator for Research and Development.

[FR Doc. 94–20682 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–M

[FRL–5055–9]

Hazardous Waste Technical Guidance Document: Determining the Integrity of Concrete Sumps (EPA/530–R–93–005)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Publication of technical guidance document.

SUMMARY: EPA announces the publication of *Technical Guidance Document: Determining the Integrity of Concrete Sumps (EPA/530–R–93–005)* and the availability of copies from the National Technical Information Service. This TGD was developed by EPA's Risk Reduction Engineering Lab (Cincinnati) in cooperation with Office of Solid Waste to provide information on conducting integrity assessments of sumps (a type of tank) in which hazardous wastes are managed.

The guidance explains how to assess the structural integrity of a hazardous waste sump that is made of concrete. First, mechanisms of concrete structural failure are discussed to provide a basis for conducting investigations. The TGD explains the steps for basic and secondary investigations, including methods for concrete inspection and sump leak testing. As part of the basic investigation, the guidance describes an approach for static head leak testing of water-filled sumps. Lastly, methods for repairing concrete and information on coatings are presented.

Even though the guidance offers very helpful information for most sumps, it does not cover all the situations that the facility owners/operators, permit writers, and inspectors may face in assessing the integrity of concrete sumps. This is especially true of very large sumps—the TGD may not provide methods that can be effectively applied to them. Additional methods may have been developed since the TGD was prepared.

Guidance Purchase

The TGD is available for purchase from the National Technical Information Service (NTIS). The NTIS order number is PB93–154631. EPA cannot provide copies. Call NTIS at (703) 487–4650 from 8:30 a.m. to 5:30 p.m. Eastern time to get an order form.

Comments

Any comments on the TGD should be sent to: Sump Guidance, Office of Solid Waste, 5304, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Please identify the document fully as: *Technical Guidance Document: Determining the Integrity of Concrete Sumps (EPA/530–R–93–005).*

Dated: August 16, 1994.

David Levy,

Waste Management Division.

[FR Doc. 94–20683 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5056–1]

Hazardous Waste Management Planning Needs and Practices: A Review of Several State Agency Approaches (EPA/530–R–93–010)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Publication of technical guidance document.

SUMMARY: EPA announces the publication of *Hazardous Waste Management Planning Needs and Practices: A Review of Several State Agency Approaches (EPA/530–R–93–010)* and the availability of copies from the National Technical Information Service. In the report EPA: examines the existing and emerging hazardous waste management planning needs of several states; describes planning practices designed to address these needs; and relates state observations on the relationship of their planning needs and activities to the Federal Capacity Assurance Planning process.

Contact

The report is available for purchase from the National Technical Information Service (NTIS). The NTIS order number is PB93–193225. EPA cannot provide copies. Call NTIS at (703)487–4650 from 8:30 a.m. to 5:30 p.m. Eastern time to get an order form.

Comments

Any comments on this report should be sent to: David Levy, Office of Solid Waste, 5302W, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Please identify the document fully as: *Hazardous Waste Management Planning Needs and Practices: A Review of Several State Agency Approaches (EPA/530–R–93–010).*

Dated: August 16, 1994.

David Levy,

Waste Management Division.

[FR Doc. 94–20684 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5056–2]

Gulf Coast Vacuum Superfund Site: Proposed de minimis Settlement

AGENCY: Environmental Protection Agency.

SUMMARY: Under Section 122(g) (4) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Environmental Protection Agency (EPA) has agreed to enter into a de minimis settlement for past and future costs at the Gulf Coast Vacuum Superfund Site in Abbeville, Louisiana, with the following parties:

Adams Resources Exploration Corp.
Amerada Hess Corp.
Avanti Services
Baroid Corp
BHP Petroleum (Americas) Inc.
BJ Titan Services
Borden Energy
Cecos International (BFI, Inc.)
Cockrell Oil Corp.
Columbia Gas Development Corp.
Columbia Gulf Transmission
Conquest Exploration Co.
Cornell Oil
Cudd Pressure Control, Inc.
Dow Chemical Co.
Dowell Schlumberger, Inc.
Dresser Industries, Inc.
Dynamic Exploration, Inc.
ENRON Oil & Gas Co. (Fl. Exploration)
Enstar Petroleum, Inc.
Exploration Co. of Louisiana
Forest Oil Corp.
Grace Energy Corporation on behalf of its subsidiaries, Grace Petroleum Corporation and Grace Drilling Company
Graham Resources, Inc.
INEXECO Oil Company
L.G.S. Natural Gas Company, Inc., (L.G.S. Exploration, Inc.)
Liberty Oil & Gas Corp.
Louisiana Gas System
Louisiana Land & Exploration Co.
Louisiana Resources Company
McMoRan Exploration
Meridan Oil, Inc.
Milpark Drilling Fluids
Mosbacher Management Co.
NERCO Oil & Gas
North American Royalties, Inc.
OXY USA, Inc.
OSCA, Inc. (Great Lakes Chemical Corp.)
Pacific Enterprises Oil Company (USA), (Pacific Royalty Co.)
Pennzoil Co.
Presidio Oil Co., Inc.
Presidio Exploration, Inc.
Rosewood Resources, Inc.
Sequa Corp. (Chromalloy Drilling Fluids)
Sonat Exploration
Tarpon of Texas
Tesoro Petroleum Distributing Co. (PEDCO)
Texaco Pipeline, Inc.
Texas Crude Oil
Total Minatome Corp.
Triumph Energy
Vulcan Materials Company for Southport Exploration, Inc.
The Western Co. of North America
Williams Exploration Co.

EPA will consider public comments on the proposed settlement for 30 days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Kathleen A, Aisling, Superfund Programs Branch, Remedial Section (6H-SA), USEPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 655–8500.

Written comments may be submitted to the person above by September 22, 1994.

Dated: July 26, 1994.

A.M. Davis,

Acting Regional Administrator, USEPA, Region 6.

[FR Doc. 94–20685 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5056–9]

Popile Inc. Site: Proposed Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: Under Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Environmental Protection Agency (EPA) has agreed to settle claims for past response costs at the Popile Inc. Site, El Dorado County, Arkansas, with the following parties:

James Cuthbertson, Popile Inc.

EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement, should comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from:

Mr. John Burleson, telephone (214) 665–6728, Cost Recovery Section (Mail Code 6H-EC), Hazardous Waste Management Division, U.S. EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

Written comments may be submitted to the person above by September 22, 1994.

Dated: August 10, 1994.

W.B. Hathaway,

Acting Regional Administrator.

[FR Doc. 94–20681 Filed 8–22–94; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Market Access Agreement

AGENCY: Farm Credit Administration.

ACTION: Notice of approval of market access agreement.

SUMMARY: The Farm Credit Administration (FCA) announces that, after taking into consideration comments from the public on the Market Access Agreement (Agreement) to be entered into by all of the banks of the Farm Credit System (System) and the Federal Farm Credit Banks Funding Corporation (Funding Corporation), the FCA has given final approval to the Agreement, subject to certain conditions.

FOR FURTHER INFORMATION CONTACT:

Jean Noonan, General Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TDD (703) 883–4444, or

James M. Morris, Senior Attorney, Regulatory Operations Division, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: The Agreement, to be entered into among each of the banks of the System and the Funding Corporation, provides that it will not be implemented until it is approved by the FCA and the Farm Credit System Insurance Corporation (FCSIC) expresses its support for the Agreement.

In February 1993 the boards of directors of the banks and the Funding Corporation approved a draft Agreement and submitted the Agreement to the FCA and the FCSIC for approval. On September 9, 1993 the FCA Board granted preliminary approval to the Agreement subject to certain conditions. Following the FCA's preliminary approval, the System banks and the Funding Corporation modified the Agreement to bring the Agreement into conformance with the FCA's conditions. The board of directors of each of the banks and of the Funding Corporation adopted resolutions whereby each party agreed to enter into the Agreement in the form submitted to the FCA, subject to the FCA's approval. The resolution of each board of directors provides that if the FCA requires modifications to the Agreement in response to public comments, the resolution shall be ineffective and the board of directors shall consider what further action to take.

On May 17, 1994, the FCA published the Agreement in the **Federal Register** (59 FR 25644) for public comment by any interested member of the public. During the comment period, which ended on June 16, 1994, comments were submitted by the Federal Land Bank Association of Yosemite, FLCA, and by the Farm Credit Bank (FCB) of Columbia on behalf of all of the System banks and the Funding Corporation.

The comment submitted by the Federal Land Bank Association of Yosemite, FLCA, stated that it was unfortunate that associations did not have the opportunity to be involved in the formulation of the Agreement and suggested two modifications to the Agreement. The association proposed that the Agreement be amended to allow "strong" associations to continue to have access to funds whenever the associations' funding bank is subject to restrictions or prohibitions on its participation in debt obligations. Second, the association recommended that the Agreement be amended to provide that when the banks receive notice that a certain bank is in category I, II, or III, all associations should receive a similar notice.

The association's first issue is an important one for associations that obtain funding from a bank subjected to sanctions under the Agreement. The association correctly points out that in the event a bank is restricted in its ability to borrow, the associations funded by that bank may need an alternative source of funds. Although this is a critical concern, it is not one that is best addressed through the Agreement. The Agreement is only designed to impose funding restrictions on banks, and cannot be used to empower other banks to lend. Moreover, the best approach to ensuring continued funding in a particular instance may require an individualized solution. The FCA and the affected institutions will have to identify the best options for continued funding, some of which may require regulatory action by the FCA or the FCSIC. In fact, a major concern of the FCA during the time that a bank is in serious financial decline is to minimize the financial impact on the bank's related associations and implement actions that will enable viable associations to continue to serve the territory in question. This need to make arrangements for viable associations was among the FCA's reasons for requiring that the Agreement provide a limited period during which the FCA could forestall the imposition of category III sanctions. For these reasons, the FCA concludes that the Agreement does not provide the appropriate vehicle for addressing this significant issue.

With regard to the association's second suggestion, the FCA concurs that associations receiving their funding from a bank in financial trouble should receive a notice when that bank is subject to category I, II, or III restrictions or prohibitions. Although these associations will also receive notice of the bank's sanctions in the bank's quarterly report to shareholders, a notice under the Agreement would be more timely. However, the assertion that *all* associations should receive notices identifying a bank that is subject to any of the three categories is less compelling. The FCA notes that the Funding Corporation would be required to report the imposition of category II or III sanctions as a material condition affecting a bank in its quarterly report to investors. The FCA concludes that this and other information in the public domain will provide adequate information to associations that are not affected directly by a bank's restricted access to funding. Accordingly, the FCA Board conditions its final approval of the Agreement on an amendment that would provide notice to associations receiving funding from a bank that is subject to category I, II, or III restrictions or prohibitions.

The comment submitted by the Farm Credit Bank of Columbia on behalf of all of the System banks and the Funding Corporation expressed the "strong and continuing support of the banks and the Funding Corporation" for the Agreement. However, in light of FCA's publication of proposed regulations governing disclosures to investors on February 4, 1994, subsequent to the development of the Agreement, the FCB of Columbia suggested that the Agreement be amended to expand its scope to include both consolidated as well as Systemwide debt obligations. The banks noted that the FCA stated in its proposed regulations that banks are jointly and severally liable on consolidated obligations as well as Systemwide obligations. *See* 59 FR 4341, Feb. 4, 1994, proposed § 630.3(f).

The commenter stated that, while the banks and the Funding Corporation do not concede that all banks are, without further action, jointly and severally liable on consolidated obligations, they believe that because the purpose of the Agreement was to cover all debt obligations on which such liability attaches, the Agreement should be amended to specifically encompass both types of obligations.

Through the issuance of the disclosure regulations, the FCA clarified that the statutory provisions governing joint and several liability contained in section 4.4 of the Farm Credit Act of 1971, as amended (Act), apply equally to consolidated and Systemwide obligations. Given the purposes of the Agreement, it is appropriate for the Agreement to be amended to treat both types of obligations in the same manner. Accordingly, the Agreement should be amended to replace the term "Systemwide Debt Securities" with the term "Debt Securities," which should be defined to include both Systemwide and consolidated obligations. In raising this issue, the commenter stated that the banks and the Funding Corporation are not "conceding" that all banks are, without further action, jointly and severally liable on consolidated obligations, and proposed that the Agreement refer to "potential liability" on "Debt Securities." Although the FCA does not share the commenter's doubt about the extent of liability for consolidated debt, the proposed modification of the Agreement is acceptable.

Having given interested parties notice and the opportunity to comment on the Agreement, the FCA Board hereby approves the Agreement pursuant to sections 4.2(d) and 4.9(b)(2) of the Act, with the following conditions:

1. The Agreement is amended by removing the term "Systemwide Debt Securities" throughout the Agreement and adding in its place the term "Debt Securities," and by adding the following definition to Article I: *Debt Securities* means Systemwide and Consolidated Obligations issued through the Funding Corporation within the meaning of sections 4.2(c) and (d) and 4.9 of the Act.

2. Section 1.09 of the Agreement is amended by adding the words "all associations discounting with or otherwise receiving funding from a bank that is in category I, II, or III," after "all Banks."

The FCA's approval of this Agreement is conditioned on the banks and the Funding Corporation amending the Agreement to make these changes and the board of directors of each institution then approving the amended Agreement. Neither the Agreement nor FCA approval of it shall in any way restrict or qualify the authority of the FCA or the FCSIC to exercise any of the powers, rights, or duties granted by law to the FCA or the FCSIC. Finally, the FCA retains the right to modify or revoke its approval of the Agreement at any time.

Dated: August 17, 1994.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 94-20687 Filed 8-22-94; 8:45 am]

BILLING CODE 6705-01-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

August 17, 1994

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857-3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 418-0214. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, Room 10214 NEOB, Washington, DC 20503, (202) 395-3561.

OMB Number: 3060-0457

Title: Amendment of Part 22 of the Commission's Rules to Establish Standards for Conducting Comparative Cellular Renewal Proceedings (CC Docket No. 90-358)

Action: Revision to a currently approved collection

Respondents: Businesses or other for-profit (including small businesses)

Frequency of Response: On occasion reporting requirement

Estimated Annual Burden: 110 responses; 19.81 hours average burden per response; 2,180 hours total annual burden

Needs and Uses: In the Memorandum Opinion and Order on Further Reconsideration (Further Reconsideration Order), the Commission revised certain rules governing the conduct of comparative renewal proceedings in the cellular radio service. Section 22.942(d) is amended to explicitly state that if a waiver of the step one hearing is granted, a renewal expectancy issue will be designated as part of the step two hearing and will be the most important comparative factor in deciding the case. This rule section is also revised to require challenging applicants to file requests for waiver of step one hearings at the time they file their applications and to allow other parties to respond to those requests at the same time that petitions to deny any of the applications are filed, i.e., thirty days after the renewal applicant files its renewal expectancy showing. Section 22.942(a) of the rules is revised to provide that renewal applicants will have sixty days after the issuance of the Public Notice announcing the filing of competing applications to file their renewal expectancy showing, rather than the thirty (30) days now specified in the rules. Section 22.942(f) of the rules is amended to state specifically that the expedited hearing procedures of Sections 22.916(b)(5)-(8) of the rules apply to step one hearings as well as to step two hearings. Section 22.941(b)(4) of the rules was amended to eliminate the language which required the disclosure of non-FCC misconduct as part of a licensee's renewal expectancy showing. The Commission also vacated the character reporting requirements set forth in footnote six of the Reconsideration Order, observing that the issue of what character reporting requirements should be imposed on cellular renewal applicants and other Part 22 applicants can be best resolved in a broad rulemaking proceeding and not on reconsideration of the cellular renewal rules. The instructions to the renewal application form (FCC Form 405) do not specifically require the submission of any character information concerning the renewal applicant. However, in response to item 8 on FCC Form 405, renewal applicants must reference its most recently filed FCC Form 401 or FCC Form 430 by file numbers, date filed, and any other relevant questions concerning the general character qualifications of the applicant. If there have been changes in the information submitted since the referenced form was filed, the renewal applicant must indicate those changes in a separate exhibit. (See paragraph 22 in the Further Reconsideration Order and

also the Public Notice entitled, "Information Regarding Cellular Renewal Applications" enclosed in this OMB submission.) The information will be used by Commission staff to conduct comparative renewal proceedings. The rules and requirements have been designed to prevent possible abuses by speculative applicants who might file competing applications against renewal applications solely to extract payments from the existing licensees. With these rules we intend to deter the filing of speculative applications by thinly or noncapitalized entities having little interest in providing cellular service. These rules will also maximize the utilization of the Commission's resources. The revisions made in the Further Reconsideration Order are needed to establish and explain several procedural aspects of comparative renewal proceedings in the cellular radio service. The intent is to promote efficiency and fairness in the licensing of the cellular radio service.

Federal Communications Commission.

LaVera F. Marshall,

Acting Secretary.

[FR Doc. 94–20597 Filed 8–22–94; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), announcement is made of the following meeting of a contract proposal review panel scheduled during the month of August 1994:

Name: Health Care Policy and Research Special Emphasis Panel, "Development of Clinical Practice Guideline on Acute Myocardial Infarction".

Dates and Times: August 23, 1994, 2:00 p.m.

Place: Agency for Health Care Policy and Research Executive Office Center 2101 East Jefferson Street 6th Floor Conference Room Rockville, MD 20852

This meeting will be closed to the public.

Purpose: The Panel's charge is to provide advice and recommendations to the Secretary and to the Administrator, Agency for Health Care Policy and Research (AHCPR), regarding the scientific and technical merit of contract proposals submitted in response to a specific Request for Proposals (282–94–2009). The purpose of the contract, entitled Development of Clinical Practice Guideline, Medical Review Criteria, Standards of Quality, and Performance Measures on Acute Myocardial Infarction, is to develop a clinical practice guideline on myocardial infarction and, based on this guideline, to develop medical review criteria, standards of quality and performance measures.

Agenda: The session of this panel will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to a specific Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This is necessary to protect the free exchange of views and avoid undue interference with panel and Department operations, and safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during the sessions. This is in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, Department regulations, 45 CFR section 11.5(a)(6), and procurement regulations, 48 CFR section 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Francis Chesley, M.D., Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, Willco Building, 6000 Executive Blvd., Suite 310, Rockville, Maryland 20852, (301) 594–4015.

Dated: August 15, 1994.

Clifton R. Gaus, Sc. D.,

Administrator.

Note: Due to unforeseen circumstances, arrangements for this meeting were delayed. Consequently, more timely notification was not possible.

[FR Doc. 94–20701 Filed 8–22–94; 8:45 am]

BILLING CODE 4160–90–P

Notice of Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), announcement is made of the following meeting of a contract proposal review panel scheduled during the month of August 1994:

Name: Health Care Policy and Research Special Emphasis Panel, "Development of Clinical Practice Guideline on Prevention of Osteoporosis".

Dates and Times: August 23, 1994, 9:00 a.m.

Place: Agency for Health Care Policy and Research, Executive Office Center, 2101 East Jefferson Street, 6th Floor Conference Room, Rockville, MD 20852.

This meeting will be closed to the public.

Purpose: The Panel's charge is to provide advice and recommendations to the Secretary and to the Administrator, Agency for Health Care Policy and Research (AHCPR), regarding the scientific and technical merit of contract proposals submitted in response to a specific Request for Proposals (282–94–2013). The purpose of the contract, entitled Development of Clinical Practice Guideline, Medical Review Criteria, Standards of Quality, and Performance Measures on Prevention of Osteoporosis, is to develop a clinical practice guideline on the prevention of osteoporosis and, based on this guideline, to develop medical review criteria, standards of quality and performance measures.

Agenda: The session of this panel will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to a specific Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This is necessary to protect the free exchange of views and avoid undue interference with panel and Department operations, and safeguard confidential proprietary information and personal information concerning individuals associated with the proposals that may be revealed during the sessions. This is in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, Department regulations, 45 CFR section 11.5(a)(6), and procurement regulations, 48 CFR section 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Jean Slutsky, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, Willco Building, 6000 Executive Blvd., Suite 310, Rockville, Maryland 20852, (301) 594–4015.

Dated: August 15, 1994.

Clifton R. Gaus, Sc. D.,

Administrator.

Note: Due to unforeseen circumstances, arrangements for this meeting were delayed. Consequently, more timely notification was not possible.

[FR Doc. 94–20700 Filed 8–22–94; 8:45 am]

BILLING CODE 4160–90–P

Centers for Disease Control and Prevention

[CDC–399]

Physician HIV Prevention Kit

Summary

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1994 funds for an unsolicited proposal submitted by the American Medical Association (AMA). The proposal is to be funded as a grant to AMA for the purposes of developing a kit and materials to encompass a range of information and behavior change tools for primary care physicians in the prevention of HIV in their patients. Approximately $75,000 is available in FY 1994 to fund this grant. It is expected that the award will begin on September 30, 1994, and will be made for a 12-month budget/project period. The funding estimate is subject to change.

The purpose of this grant is for the AMA to develop a Physician HIV Prevention kit. The kit is to include easy-to-use behavior change techniques for use in the physician's office. The requirements to implement these patient-assistance techniques for behavior change are to vary along three major dimensions: time (0, 30 seconds, 2 minutes), staff (physician, nurse/PA, clerical), and resources (none, reusable kit items, expendable/renewable kit items). The kit and materials will encompass a wide range of information and behavior change support for patients. It will supply the tools necessary to encourage and sustain "prevention behaviors," or "healthy living." It is proposed that the physician will select from the kit the item(s) relevant to the patient's needs and preferences.

The AMA proposes the kit include information on behavioral techniques for those who are sexually active and those who choose abstinence, as well as items such as a poster with accompanying brochures that encourage all patients to be health educators to family, friends, and loved ones; a condom demonstration item; a behavior change diary; and contracting forms.

AMA will test the kit through a State medical society. It will train 100–200 primary care physicians in the use of the kit. The State medical society will provide renewable items for the kit, as well as a mechanism to respond to prevention questions from physicians in the trial group. It will also be the responsibility of the State medical society to collect outcome data on the efficacy of the program and kit. The State medical society will also maintain regular contact with the project-trained physicians to gather information on successes and solutions to prevention problems they experience.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of HIV Prevention. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

Authority

This project is authorized under section 317(k)(2)(D) of the Public Health Service Act [42 U.S.C. 247b (k)(2)(D)], as amended.

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Eligible Applicant

Assistance will be provided only to the American Medical Association (AMA) for this project. No other applications are solicited.

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.939.

Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please refer to Announcement Number 399 and contact Elizabeth M. Taylor, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E–16, Atlanta, Georgia 30305, telephone (404) 842–6640.

A copy of "Healthy People 2000" (Full Report, Stock No. 017–001–00474–0) or "Healthy People 2000" (Summary Report, Stock No. 017–001–00473–1) referenced in the "Summary" may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: August 17, 1994.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC)

[FR Doc. 94–20592 Filed 8–22–94; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 94N–0304]

Sandoz Pharmaceuticals Corp.; Bromocriptine Mesylate (Parlodel) for the Prevention of Physiological Lactation; Opportunity for a Hearing on a Proposal To Withdraw Approval of the Indication

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of those parts of the new drug application (NDA) for Parlodel (bromocriptine mesylate) that pertain to the prevention of physiological lactation. NDA 17–962 is held by Sandoz Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936 (Sandoz). The basis for the action is a reevaluation finding that this drug product is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

DATES: A hearing request is due on or before September 22, 1994; data and information in support of the hearing request are due on or before October 24, 1994.

ADDRESSES: A request for hearing, supporting data, and other comments are to be identified with Docket No. 94N–0304 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information on medical/scientific issues: Solomon Sobel, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3490.

For general information concerning this notice: Harry T. Schiller, or David T. Read, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Estrogens were used in the treatment of postpartum breast engorgement beginning in the 1940's. In the 1970's, FDA and what is now the Fertility and Maternal Health Drugs Advisory Committee (the Committee) became concerned about mounting evidence, presented in diverse studies, scientific publications, and adverse drug experience (ADE) reports received by

FDA's Spontaneous Reporting System (SRS), suggesting that these estrogen-containing drug products were of questionable effectiveness for this indication because of rebound lactation, and possibly unsafe because of an increased risk of thromboembolism.

In January 1978, the Committee considered whether bromocriptine, a nonestrogen, should be labeled for the prevention of physiological lactation. It recommended against approval of the indication at that time because insufficient studies had been done to show safety and effectiveness.

Subsequently, FDA reviewed Sandoz's supplemental new drug application for Parlodel, in which Sandoz sought approval for a new indication for use of the drug for the prevention of physiological lactation. NDA 17-962 for Parlodel (bromocriptine) was originally approved on June 28, 1978, for the temporary relief of amenorrhea-galactorrhea due to nonpituitary tumor etiology. Sandoz submitted studies on bromocriptine that showed evidence of effectiveness in the prevention of physiological lactation without any reports of serious adverse experiences in the study population. FDA approved the supplement for the new indication in 1980 to provide the medical community with what was then believed to be a safer therapeutic alternative to existing estrogen-containing drug products labeled for similar indications; e.g., to prevent painful swelling of the breasts after pregnancy, and to prevent postpartum breast engorgement.

By 1983, after bromocriptine had been used for the prevention of physiological lactation in the general population, a number of serious ADE's (see 21 CFR 314.80(a)) were reported in association with this use. The ADE's at that time included six reports of severe hypertension, three reports of hypertension and seizures, three reports of seizures, and three reports of hypertension and strokes. Because of the seriousness of these ADE's, in May 1983 FDA sought, but was unable to obtain, Sandoz's agreement to include a warning of these adverse experiences in Parlodel's labeling.

In April 1984, in its "Drug Bulletin," FDA reported the ADE's for bromocriptine associated with use of that drug in the prevention of physiological lactation.

In March 1985, FDA again requested Sandoz to list and update certain serious adverse experiences in Parlodel's labeling, but Sandoz did not agree to make the labeling changes.

In February 1987, FDA requested for a third time that Sandoz change its labeling to include the serious adverse experiences and also requested that Sandoz send a letter to doctors to alert them to the potential hazards of using bromocriptine for the prevention of physiological lactation. In April 1987, Sandoz agreed to and implemented both requests.

FDA received additional reports of serious ADE's and the agency presented them to the Committee in June 1988 (Ref. 1). These ADE reports included 5 reports of isolated hypertension, 26 reports of seizures, 3 reports of status epilepticus seizures, and 9 reports of stroke, all of which followed the use of bromocriptine for the prevention of physiological lactation. Before offering a recommendation to FDA, the Committee elected to wait for the results of Sandoz's then ongoing study entitled "An Epidemiologic Evaluation of the Possible Relation Between Bromocriptine, Puerperal Seizures and Stroke" (the ERI study).

In June 1989, the Committee reconsidered bromocriptine in light of the final results from Sandoz's ERI study, published at a later date (Ref. 2). The ERI study failed to allay the concerns of the agency or the Committee regarding the drug's association with seizures. Additionally, the ERI study was too small in size to characterize adequately the risk of stroke.

At the 1989 Committee meeting, FDA reported the ADE's associated with bromocriptine reported to FDA as of that date, including 28 reports of hypertension, 36 reports of seizures, and 19 reports of cerebrovascular accidents (CVA's). FDA reported that it had received a total of 85 serious ADE's, including 10 deaths, since approval of the indication in 1980. The agency concluded that, although the individual ADE's did not prove that bromocriptine caused hypertensive crises, seizures, or CVA's, in the aggregate, the ADE's suggested that bromocriptine may be the cause of these serious adverse experiences, therefore warranting further consideration by the Committee.

The Committee recommended that none of the drugs then labeled for use in lactation suppression, including bromocriptine, should be used for this indication. The Committee concluded that the possibility that these drug products may cause serious adverse experiences in some patients outweighs the limited benefit of their use in a self-resolving condition that can be managed by more conservative treatment (Ref. 3).

FDA agreed with the Committee's recommendation and asked all manufacturers of drug products labeled for use in preventing physiological lactation to remove voluntarily that indication from their products' labeling. All manufacturers but Sandoz complied with the request.

In September 1989, FDA again requested Sandoz to withdraw voluntarily Parlodel's indication for the prevention of physiological lactation and indicated the agency's intent to initiate proceedings to withdraw approval of the indication if Sandoz refused. Sandoz declined to remove the indication and, on April 23, 1990, filed a citizen petition requesting that FDA reconsider its decision to initiate withdrawal proceedings.

The Director of the Center for Drug Evaluation and Research (the Director) has evaluated the evidence suggesting that bromocriptine may cause hypertension, seizures, and CVA's in some patients using the drug for prevention of postpartum lactation suppression, and concludes that these risks outweigh the product's marginal benefit in preventing postpartum lactation. Accordingly, the Director is proposing to withdraw approval of the indication recommending bromocriptine for preventing physiological lactation on the basis that the drug is no longer shown to be safe for this indication. A full discussion follows.

II. The Effectiveness of Bromocriptine in the Prevention of Physiological Lactation

On October 27, 1978, Sandoz submitted to FDA a supplement to its NDA for Parlodel proposing the drug's use in preventing physiological lactation. This supplement included 24 studies (12 domestic and 12 foreign) using a total of 747 patients. In these studies, 568 patients received bromocriptine, and 179 received estrogens or placebo. Based on these studies, FDA concluded that bromocriptine is effective for the prevention of physiological lactation.

The Director has reevaluated these studies and concludes that the benefit of using bromocriptine to prevent physiological lactation is limited by a number of factors.

First, the benefit of using a pharmacologically active systemic drug for up to 3 weeks to prevent lactation, a self-limiting condition that generally lasts no longer than a few days, is highly questionable. Without the stimulation of breast feeding, the ability to lactate disappears rapidly. The onset of engorgement occurs 48 to 72 hours after delivery, and engorgement usually disappears in 1 to 2 days. Secretion usually disappears after approximately 4 days, although it may last up to 7 days. Maximum discomfort occurs

between 2 to 7 days after delivery, but most patients are uncomfortable for only the first 24 hours of this period.

Conservative treatment entails the use of nonpharmacological aids such as ice packs and breast binding to suppress lactation, provide relief from discomfort, and shorten the duration of painful engorgement or leaking. Patients also can be treated with analgesics to provide additional relief.

In one study, only 13 percent of placebo patients reported moderate or severe breast engorgement during the postpartum period, and only 9 percent of placebo patients used analgesics (propoxyphene and codeine) for pain relief (Ref. 4). A review of a number of studies concluded that the majority of women can be adequately treated with a tight brassiere, avoidance of nipple stimulation, and, if needed, minor analgesics (Ref. 5). These studies also show that up to 30 percent to 40 percent of women may remain in some discomfort and require stronger analgesics for the first days after parturition, but, ultimately, all women can achieve a substantial level of comfort through the use of conservative therapy.

Moreover, bromocriptine is effective for lactation suppression only if prescribed before lactation begins. Because the small number of women who will require stronger analgesics for breast symptoms cannot be identified in advance, the large majority of women who are exposed to bromocriptine for this use assume the risks of the product without the potential for meaningful benefit.

Second, the benefit of using bromocriptine is called into question by the fact that a large number of patients experience rebound lactation after discontinuing use of the drug. In many cases, therefore, bromocriptine merely delays lactation.

In its original analysis in 1980 of the studies supporting approval of bromocriptine for lactation suppression, FDA concluded that 18 to 40 percent of the women taking bromocriptine reported some breast soreness, leaking, or engorgement after stopping use of the drug. The actual number of patients experiencing rebound lactation after taking bromocriptine and the severity of their symptoms are difficult to assess because Sandoz's studies presented incomplete information on rebound lactation.

Thus, the evidence shows that the serious risks associated with the use of bromocriptine to suppress lactation are unacceptable given that lactation can be suppressed without risk by the use of more conservative, nonpharmacological treatments occasionally supplemented with mild analgesics.

III. Safety of Bromocriptine for the Prevention of Physiological Lactation

The use of bromocriptine has been associated with both minor and serious adverse experiences. In the domestic clinical trials supporting the original approval of bromocriptine for preventing physiological lactation, 22.8 percent of the patients taking bromocriptine reported at least one adverse experience. The majority of these adverse experiences were headache (8.5 percent of the patients), nausea (8.1 percent), dizziness (7.4 percent), vomiting (2.9 percent), and rash (2.6 percent). Four of the 10 bromocriptine patients who dropped out of the study did so because of drug-related side effects.

In the foreign studies supporting approval, 5 percent of the patients receiving bromocriptine reported adverse experiences. These adverse experiences were of the same general nature as the adverse experiences reported by the American patients.

The most important adverse experience reported by investigators was hypotension (low blood pressure). A lowering of blood pressure equal to or greater than 20 conventional millimeters of mercury (mmHg) systolic and 10 mmHg diastolic was observed in 28.4 percent of all patients receiving the drug. Analysis showed that the hypotension was both dose- and time-related, with the most significant hypotension appearing within 4 hours.

Based on this information, FDA originally concluded that the side effects associated with bromocriptine were minor or could be controlled through appropriate labeling. Significantly, at the time of approval there were no reports of hypertensive crises, seizures, or CVA's in either the American or the foreign studies. Therefore, FDA approved the drug as safe for use in preventing physiological lactation.

Since approval, a number of serious adverse drug experiences associated with the use of bromocriptine in postpartum women have been reported to FDA and have appeared in the medical literature. These serious adverse experiences have included hypertension, seizures, and CVA's.

A. Hypertension

In 1989, the agency reported to the Committee that it had received 28 hypertension ADE's associated with bromocriptine's use in postpartum women, including 3 reports in 1988 of new-onset hypertension in women who had not been preeclamptic. Hypertension was accompanied by severe headaches in two of the three women. Two of the three women had no history of hypertension, while the third woman had previously presented only borderline elevations in the diastolic readings. In two of the three women, there was no evidence of confounding by concomitant medication.

As of September 1993, FDA had received 77 domestic spontaneous reports of hypertension in postpartum women 15 through 45 years of age who used bromocriptine for lactation suppression.

In 1989, Watson and associates reported on a study of the relationship between hypertension and the use of bromocriptine in postpartum women (Ref. 6; data from this study were presented to the Committee in 1988 prior to publication). This was a retrospective study based on data obtained after hospital discharge from 1,813 patients, 1,320 of whom were taking bromocriptine for lactation suppression. Data were obtained 3 to 21 days after delivery.

Hypertension was defined, for study purposes, as systolic pressure of 140 mmHg or more, or diastolic pressure of 90 mmHg or more. The use of bromocriptine was the independent variable and postpartum hypertension was the dependent variable. Covariates were age, race, parity, weight, chronic hypertension, pregnancy-induced hypertension, and antihypertensive medication. Data were analyzed by discriminant analysis.

Although bromocriptine use alone was not found to be a significant factor, the investigators concluded that the use of bromocriptine by women who had previously exhibited pregnancy-induced hypertension contributed significantly ($p < 0.01$) to a higher risk for the development of postpartum hypertension.

Also in 1989, Ruch and Duhring reported on a 27-year-old woman with pregnancy-induced hypertension who had taken bromocriptine for lactation suppression (Ref. 7). Eight days after starting bromocriptine, she presented with severe hypertension followed by cardiac arrest and death. An autopsy revealed no evidence of coronary atherosclerosis. However, the autopsy did show a 60 to 70 percent stenotic plaque in the left anterior descending artery, which the authors described as likely to have been secondary to a coronary artery spasm induced, at least partially, by bromocriptine.

Kulig and associates reported on two women who developed severe headaches after taking bromocriptine for

lactation suppression in 1991 (Ref. 8). The use in addition to bromocriptine of a therapeutic sympathomimetic agent resulted in ventricular tachycardia and cardiac dysfunction in one case and seizures and cerebral vasospasm in the other.

B. Seizures

FDA presented an analysis of 29 seizure ADE reports from the SRS to the Committee in 1988: 16 reports were of grand mal seizures, 3 reports were of status epilepticus, 1 report was of a focal seizure, and 9 reports were of seizures not otherwise specified.

Fourteen of the 29 postpartum patients had no prior history of seizures. One patient previously had a single isolated seizure associated with pericarditis. Information on hypertension was available on 18 patients: 17 had no history of hypertension, and 1 previously had a blood pressure reading of 160/90 immediately postpartum.

Information on concomitant medication was available for 25 of the 29 patients. Six were not taking any medication at the time of their seizures. Nineteen were taking a variety of medications, including antibiotics for caesarean section infection prophylaxis or treatment of endometritis, narcotic and over-the-counter analgesics for postpartum pain or headache, and diet pills. One patient was reportedly using cocaine just prior to her seizure.

Status epilepticus was examined separately because it is a potentially life-threatening condition. Three seizure cases were diagnosed as status epilepticus by the reporting physicians. Three other cases, initially reported as grand mal seizures, also met the clinical profile of status epilepticus (Ref. 9). All six women had unremarkable pregnancies and deliveries. Five of the six had a negative seizure history. The status of the remaining patient is unknown. None of the six was reported to have had blood pressure problems prior to using bromocriptine.

In its summary to the Committee of seizure reports through 1988, FDA noted that the onset of seizures tended to occur around 5 to 6 days after bromocriptine use began.

In 1989, FDA updated the Committee on seven new ADE's received in the preceding year involving women 18 to 36 years old. Six of the seven began taking bromocriptine for the prevention of physiological lactation 3 to 8 days prior to their seizures. In the seventh case, there was no information on how long the patient had taken bromocriptine before seizure. Six of the seven had no history of preeclampsia. Five of the seven had no underlying medical conditions. Two had also taken Percocet, two had received a nonsteroidal anti-inflammatory drug for pain, and one woman had received pseudoephedrine. Five of the seven recovered completely. The long-term outcome for the other two is unknown. In these cases, seizures occurred 5 to 10 days after postpartum bromocriptine use.

A similar clustering effect with a mean time of 6 days was also noted in an agency followup investigation of seizure ADE's from the start of marketing in 1980 through September 1993. To date, the agency has received 63 domestic reports of seizures in women taking bromocriptine for the prevention of physiological lactation, plus one report of a seizure in a nursing 2-year-old whose mother had taken bromocriptine. In 27 of these 64 reports, there was no mention of any confounding factors such as a history of seizures or eclampsia. Although many of these patients received anticonvulsant medication, and the outcome was not reported for many patients, withdrawal of the drug resulted in no further seizures in all but three patients. Seizures were often preceded by a headache or accompanied by hypertension, blurred vision, or loss of vision. Clinicians described these seizures as grand mal or tonic-clonic. When performed, electroencephalograms and computed tomography scans were normal.

Sandoz's ERI study noted an association between late occurring seizures and bromocriptine. The results from this study were reported to the Committee in 1989. This retrospective study reviewed hospital records showing medical diagnostic codes indicative of seizure and stroke.

The rarity of seizures, the small number of cases examined, and the study's resultant lack of statistical power severely reduce its usefulness in providing epidemiologic information. At only one of three sites were patient identifiers used that allow investigators to track the histories of individual patients for complete case ascertainment, including, most importantly, readmissions. If the use of bromocriptine for the prevention of physiological lactation causes late-occurring seizures, seizures attributable to bromocriptine use would be most likely to occur after hospital discharge. The lack of readmission data suggests a possible bias towards cases under-ascertainment in the ERI study's raw data and conclusions.

During the first 3 days of bromocriptine therapy, the ERI study reported 22 percent fewer seizures among women taking bromocriptine than in postpartum nonbromocriptine users. The authors of the study conclude that this reduction in seizure risk is due to a protective effect from bromocriptine. However, because this was a retrospective study rather than a clinical trial, the study's patients were not randomly assigned to bromocriptine and placebo groups. Therefore, another explanation for the reduced number of early seizure reports may be patient selection; doctors may well be less likely to prescribe bromocriptine for ill patients.

The ERI study also reported that, after 3 days, women on bromocriptine therapy for the prevention of physiological lactation faced a 1.6 times greater than normal risk of seizures, even when controlled for seizure history. The suggestion by the authors of the study that bromocriptine may delay seizures, thereby shifting some early-onset seizures so that they became late-onset seizures, is unsubstantiated. Moreover, even if bromocriptine delays seizures, such an effect is potentially dangerous if it delays seizures from a time when patients are monitored in a hospital to a time when patients are ordinarily at home without constant medical supervision or readily available medical support.

C. CVA's

In 1988, FDA reviewed six cases of stroke associated with bromocriptine for the Committee. The agency also reported the results of a separate search of the scientific literature, which contained accounts of 44 women suffering postpartum CVA's with onset in the first 30 days after delivery.

In 1989, FDA updated the Committee on 10 additional ADE's regarding CVA's received since 1988. Three of the 10 women died while 2 others survived but remained severely disabled. Nine of the 10 cases occurred between 4 and 26 days postpartum.

These patients were between 22 and 38 years old. Information on the duration of bromocriptine use is known for all but one case. Eight patients had taken bromocriptine for lactation suppression 3 to 13 days prior to their CVA. All CVA's occurred while the patient was receiving the drug. Information on concomitant medications is known for seven patients. Five of the 10 patients took no medication other than bromocriptine, 1 also took acetaminophen, and one also took Aldomet because of a 6-year history of hypertension. The last patient also had sickle cell trait. Seven of the 10 patients had no history of preeclampsia.

One of the 10 patients had a transient ischemic attack and her physician described her as having mild toxemia on the basis of moderately elevated blood pressure and trace proteinuria. Eight patients had no significant underlying illnesses that would predispose them to a CVA.

Through September 1993, the agency had received reports of 31 cases of CVA in association with bromocriptine used for the prevention of physiological lactation. Nine patients died; 20 were hospitalized and discharged with various degrees of permanent impairment. No confounding factor was reported for 13 of the 31 patients.

The ERI study found one relatively unconfounded case of stroke involving a woman taking bromocriptine for the prevention of physiological lactation.

In 1986, Nedd and associates reported on two patients who suffered subarachnoid hemorrhages after using bromocriptine postpartum (Ref. 10). One woman had an aneurysm, while the other woman was diagnosed with a superior sagittal sinus thrombosis. She also had a history of hypertension and sickle cell trait.

In 1990, Maurel and associates reported on a case of an obese, 30-year-old woman smoker who suffered a cerebral infarction 2 weeks after beginning bromocriptine (Ref. 11). Her pregnancy and delivery were unremarkable, and the investigators could not explain the infarction by any other cause.

D. Summary of Safety Information

Since approval of bromocriptine for use in preventing physiological lactation, FDA has received a number of reports of serious and life-threatening adverse experiences (hypertension, seizures, and CVA's) associated with the use of bromocriptine for this indication. FDA believes that the number of women experiencing such adverse experiences may well be greater than those reported to FDA.

The above evidence, in aggregate, calls into question bromocriptine's safety for use in postpartum women given that bromocriptine may be responsible for hypertension, seizures, and CVA's in a small but significant number of patients. Moreover, bromocriptine may be an additional risk factor in patients who are already at risk for seizures and stroke.

In addition, a possible mode of action exists for these adverse events. In the general population, a risk factor for hypertensive crises and spasms is exposure to ergot alkaloids. Bromocriptine is a semi-synthetic ergot alkaloid. Bakht and associates have suggested that a subpopulation may exist in which bromocriptine exerts vasospastic effects similar to other ergot alkaloids (Ref. 12).

Pregnancy-induced hypertension is also known to be a catecholamine-sensitive disorder. Bromocriptine is a dopaminergic agonist and is structurally similar to dopamine, a catecholamine nucleus. It is therefore possible that bromocriptine may act as an adrenergic stimulant, like other ergot alkaloids, and precipitate pregnancy-induced hypertension or other related adverse events.

Moreover, the clustering of late-onset seizure reports suggests an association between seizures and bromocriptine use in some postpartum women. In the general population, the majority of seizures in the postpartum period occur within the first 48 hours, and are generally diagnosed as eclamptic. After 3 or 4 days, seizures are viewed as unusual, suggesting a possible relationship between bromocriptine use and this adverse experience.

IV. Benefit/Risk Analysis and Conclusions

FDA approved bromocriptine in 1980 for the prevention of physiologic lactation, despite its limited benefits, to provide what appeared to be a safe, nonestrogenic therapy for this indication. At the time of approval, FDA had no knowledge of the association of serious adverse experiences with bromocriptine therapy, and believed that a drug with roughly the same therapeutic effectiveness was better than existing estrogenic therapies, which were associated with the serious adverse experience of thrombosis.

FDA now has new information suggesting that therapeutic use of bromocriptine for the prevention of physiological lactation may lead to serious adverse experiences, including death and paralysis, in a small but significant number of patients. Patients at high risk of experiencing these serious adverse experiences cannot be adequately predetermined. In light of the limited benefit of using bromocriptine for the prevention of lactation, and the effectiveness and lack of serious adverse effects of conservative treatments such as breast binding with or without mild analgesics, the risk that bromocriptine may cause a serious adverse effect in a postpartum woman is unacceptable.

Accordingly, the Director concludes that the potential risks associated with the use of bromocriptine for the prevention of physiological lactation outweigh its limited benefits and bromocriptine is no longer shown to be safe for use in preventing physiological lactation. The Director is proposing to withdraw approval of the indication recommending bromocriptine for use in the prevention of physiological lactation in accordance with section 505(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)(2)).

V. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript of the June 1988 meeting of the Fertility and Maternal Health Drugs Advisory Committee.

2. Rothman, K. J., D. P. Funch, and N. A. Dreyer, "Bromocriptine and Puerperal Seizures," *Epidemiology*, 1(3):232–238, 1990.

3. Transcript of the June 1989 meeting of the Fertility and Maternal Health Drugs Advisory Committee.

4. Niebyl, J. R. et al., "The Effect of Chlorotrianisene as Postpartum Lactation Suppression on Blood Coagulation Factors," *American Journal of Obstetrics and Gynecology*, 134(5):518–522, 1979.

5. Kochenour, N. K., "Lactation Suppression," *Clinical Obstetrics and Gynecology*, 23(4):1045–1059, 1980.

6. Watson, D. L. et al., "Bromocriptine Mesylate for Lactation Suppression: A Risk for Postpartum Hypertension?" *Obstetrics and Gynecology*, 74(4):573–576, 1989.

7. Ruch, A., and J. L. Duhring, "Postpartum Myocardial Infarction in a Patient Receiving Bromocriptine,l," *Obstetrics and Gynecology*, 74(3 Pt.2):448–451, 1989.

8. Kulig, K. et al., "Bromocriptine-Associated Headache: Possible Life-Threatening Sympathomimetic Interaction," *Obstetrics and Gynecology*, 78(5 pt.2):941–943, 1991.

9. Delgato-Escueta, A. V. et al., "Management of Status Epilepticus," *New England Journal of Medicine*, 306:1337–1340, 1983.

10. Nedd, K. J., M. Kent, and V. Powell, Jr., "Subarachnoid Hemorrhage During Pregnancy and the Puerperium: Report of 3 Cases and Review of the Literature," *Journal of the American Osteopathic Association*, 86(3):183–188, 1986.

11. Maurel, C. et al., "Acute Thrombotic Accident in the Postpartum Period in a Patient Receiving Bromocriptine," *Critical Care Medicine*, 18(10):1180–1181, 1990.

12. Bakht, F. R. et al., "Postpartum Cardiovascular Complications After Bromocriptine and Cocaine Use," *American Journal of Obstetrics and Gynecology*, 162:1065–1066, 1990.

VI. Notice of Opportunity for a Hearing

The Director has evaluated the information discussed above and, on the grounds stated, is proposing to withdraw approval of NDA 17–962 insofar as it pertains to the indication recommending the use of bromocriptine

for the prevention of physiological lactation.

Therefore, notice is given to Sandoz and to all other interested persons that the Director proposes to issue an order under section 505(e)(2) of the act, withdrawing approval of NDA 17–962, and all amendments and supplements thereto, insofar as they pertain to the indication recommending the use of bromocriptine for the prevention of physiological lactation. The Director finds that new evidence of clinical experience, not contained in the application and not available to the Director until after the application was approved, evaluated together with the evidence available to the Director when the application was approved, shows that the drug is not shown to be safe for use in the prevention of physiological lactation.

In accordance with section 505 of the act and 21 CFR part 314, the applicant is hereby given an opportunity for a hearing to show why approval of pertinent parts of the NDA should not be withdrawn.

An applicant who decides to seek a hearing shall file: (1) On or before September 22, 1994, a written notice of appearance and request for hearing, and (2) on or before October 24, 1994, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in 21 CFR 314.200 and 21 CFR part 12.

The failure of the applicant to file a timely written notice of appearance and request for a hearing, as required by 21 CFR 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that person's drug products. Any new drug product marketed without, or in any way that is not consistent with, an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of pertinent parts of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: August 15, 1994.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 94–20562 Filed 8–17–94; 3:39 pm]

BILLING CODE 4160–01–P

National Institutes of Health

Division of Research Grants; Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panels (SEPs) meetings:

Purpose/Agenda: To review Small Business Innovation Research Program grant applications.

Name of SEP: Clinical Sciences.
Date: December 6–7, 1994.
Time: 8:00 a.m.
Place: Ramada, Rockville, MD.
Contact Person: Dr. Gertrude McFarland, Scientific Review Admin., 5333 Westbard Ave., Room 352, Bethesda, MD 20892, (301) 594–7080.

Purpose/Agenda: To review individual grant applications.

Name of SEP: Multidisciplinary Sciences.
Date: September 12, 1994.
Time: 8:30 a.m.
Place: Ritz Carlton, Tysons Corner, VA.
Contact Person: Dr. Eileen Bradley, Scientific Review Admin., 5333 Westbard Ave., Room 2A10, Bethesda, MD 20892, (301) 594–7188.

Name of SEP: Biological & Physiological Sciences.
Date: October 5, 1994.
Time: 1:00 p.m.
Place: NIH, Westwood Bldg., Room 233B, Telephone Conference.
Contact Person: Dr. Ramesh Nayak, Scientific Review Administrator, 5333 Westbard Ave., Room 233B, Bethesda, MD 20892, (301) 594–7169.

Name of SEP: Microbiological and Immunological Sciences.
Date: October 6, 1994.
Time: 7:00 p.m.
Place: Boniventure Hotel, Fort Lauderdale, FL.
Contact Person: Dr. Marcel Pons, Scientific Review Administrator, 5333 Westbard Ave., Room A13, Bethesda, MD 20892, (301) 594–7210.

Name of SEP: Chemistry Research Special Emphasis Panel.
Date: October 12, 1994.
Time: 8:30 a.m.
Place: St. James Hotel, Washington, DC.
Contact Person: Dr. Edward Zapolski, Scientific Review Administrator, 5333 Westbard Ave., Room 335, Bethesda, MD 20892, (301) 594–7302.

Name of SEP: Clinical Sciences.
Date: October 14, 1994.
Time: 10:00 a.m.
Place: American Inn, Bethesda, MD.
Contact Person: Dr. Joseph Kaiser, Scientific Review Administrator, 5333 Westbard Ave., Room 206B, Bethesda, MD 20892, (301) 594–7241.

Name of SEP: Clinical Sciences.
Date: October 21, 1994.
Time: 11:00 a.m.
Place: American Inn, Bethesda, MD.
Contact Person: Dr. Fred Marozzi, Scientific Review Administrator, 5333 Westbard Ave., Room 205, Bethesda, MD 20892, (301) 594–7278.

Name of SEP: Clinical Sciences.
Date: October 25–27, 1994.
Time: 8:00 a.m.
Place: Ramada Inn, Rockville, MD.
Contact Person: Dr. Gertrude McFarland, Scientific Review Admin., 5333 Westbard Ave., Room 352, Bethesda, MD 20893, (301) 594–7080.

Name of SEP: Microbiological and Immunological Sciences.
Date: October 27, 1994.
Time: 8:00 a.m.
Place: Holiday Inn, Bethesda, MD.
Contact Person: Dr. Jean Hickman, Scientific Review Administrator, 5333 Westbard Ave., Room 235, Bethesda, MD 20892, (301) 594–7078.

Name of SEP: Biological and Physiological Sciences.
Date: November 3–4, 1994.
Time: 8:30 a.m.
Place: American Inn, Bethesda, MD.
Contact Person: Dr. Nicholas Mazarella, Scientific Review Admin., 5333 Westbard Ave., Room 222B, Bethesda, MD 20892, (301) 594–7098.

Name of SEP: Multidisciplinary Sciences.
Date: November 7–9, 1994.
Time: 8:00 a.m.
Place: Crowne Plaza, Rockville, MD.
Contact Person: Dr. Bill Bunnag, Scientific Review Administrator, 5333 Westbard Ave., Room 2A07A, Bethesda, MD 20892, (301) 594–7360.

Name of SEP: Multidiscipinary Sciences.

Date: November 14–15, 1994.
Time: 8:00 a.m.
Place: Crowne Plaza, Rockville, MD.
Contact Person: Dr. Bill Bunnag, Scientific Review Administrator, 5333 Westbard Ave., Room 2A07A, Bethesda, MD 20892, (301) 594–7360.

The meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: August 18, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94–20680 Filed 8–22–94; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of application.

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C., *et seq.*)

PRT–667512

Applicant: Dr. Howard Shellhammer, San Jose, CA

The applicant requests amendment of his permit to take (harass, capture, handle, and release) the salt marsh harvest mouse (*Reithrodontomys raviventris*) for scientific research to include Alameda, Contra Costa, Marin, Napa, Sacramento, San Francisco, San Mateo, Santa Clara, Solano, and Sonoma Counties, California.

PRT–789266

Applicant: Ms. Patricia Hobell, Oceanside, CA

The applicant requests amendment of her permit to include take (harassment) of the Western snowy plover (*Charadrius alexandrinus*) and the California Least Tern (*Sterna albifrons brownii*) for scientific research in Orange and San Diego Counties, California.

PRT–793647

Applicant: Ms. Mary Perry, Santa Maria, CA

The applicant requests a permit to take (harass) the Western snowy plover (*Charadrius alexandrinus*) and the California Least Tern (*Sterna albifrons brownii*) for scientific research in San Luis Obispo and Santa Barbara Counties, California.

PRT–793646

Applicant: The Falcon Research Group, Bow, WA

The applicant requests a permit to take (harass, capture, handle, band, and release) peregrine falcon (*Falco peregrinus*) for scientific research in western Washington State.

PRT–793644

Applicant: Dr. Camm C. Swift, Arcadia, CA

The applicant requests a permit to take (harass, capture, handle, release, and retain specimens) the tidewater goby (*Eucyclogobius newberryi*) and the unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*) for scientific research in Del Norte, Humbolt, Los Angeles, Marin, Mendocino, Monterey, Santa Barbara, Santa Cruz, San Diego, San Luis Obispo, San Mateo, Sonoma, and Ventura Counties, California.

PRT–793640

Applicant: Dr. Jerry Smith, San Jose, CA

The applicant requests a permit to take (harass, capture, handle, mark, and release) the tidewater goby (*Eucyclogobius newberryi*) for scientific research in Marin, Monterey, Santa Cruz, and San Mateo Counties, California.

PRT–793645

Applicant: Mr. Don Alley, Jr., Brookdale, CA

The applicant requests a permit to take (harass, capture, handle, release) the tidewater goby (*Eucyclogobius newberryi*) for scientific research in Monterey, Santa Cruz, San Luis Obispo, and San Mateo Counties, California.

PRT–793638

Applicant: Ms. Ramona Swenson, El Cerrito, CA

The applicant requests a permit to take (harass, capture, handle and release, and retain specimens) the tidewater goby (*Eucyclogobius newberryi*) for scientific research in Alameda, Contra Costa, Del Norte, Humbolt, Los Angeles, Marin, Mendocino, Monterey, Napa, Orange, Sacramento, Santa Barbara, Santa Clara, Santa Cruz, San Diego, San Francisco, San Luis Obispo, San Mateo, Solano, Sonoma, and Ventura Counties, California.

DATES: Written comments on the permit applications must be received on or before September 22, 1994.

ADDRESSES: Written data or comments should be submitted to the Chief, Division of Consultation and Conservation Planning, Ecological Services, U.S. Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents, within 30 days of the date of publication of this notice, to the following office: Division of Consultation and Conservation Planning, Ecological Services, U.S. Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181. Phone: 503–231–2063; FAX: 503–231–6243.

Dated: August 16, 1994.

Cynthia U. Barry,

Acting Assistant Regional Director, Region 1, Portland, OR.

[FR Doc. 94–20590 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–55–P

Marine Mammals; Stock Assessment Reports

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Availability of marine mammal draft stock assessments and Potential Biological Removal workshop reports; request for comments.

SUMMARY: The Marine Mammal Protection Act (MMPA) amendments of 1994 require the Fish and Wildlife Service (Service) and the National Marine Fisheries Service (NMFS) to prepare draft stock assessments by August 1, 1994, for all marine mammal stocks that occur in waters under the jurisdiction of the United States. The NMFS, with participation by the Service, convened a workshop to develop an initial approach for promoting a consistent national interpretation of parameters used in draft stock assessments.

DATES: Comments on the draft stock assessments and the report of the PBR workshop must be received by November 21, 1994.

ADDRESSES: Copies of the draft stock assessments and PBR workshop reports are available from the Division of Fish and Wildlife Management Assistance, U.S. Fish and Wildlife Service, Room

820–ARLSQ, 4401 N. Fairfax Drive, Arlington, VA 22203, Telephone (703) 358–1718.

Comments on the draft stock assessments for polar bears, Pacific walrus, and Alaska sea otters in Alaska, along with related comments on the report of the PBR workshop, should be sent to Dave McGillivary, Supervisor, Office of Marine Mammals Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503.

Comments on the draft stock assessments for West Indian manatees, along with related comments on the report of the PBR workshop, should be sent to Robert Turner, Manatee Coordinator, U.S. Fish and Wildlife Service, 6620 South Point Drive, South, Suite 310, Jacksonville, Florida 32216.

Comments on the draft stock assessments for California sea otters and Alaska sea otters in Washington State, along with related comments on the report of the PBR workshop, should be sent to Carl Benz, Sea Otter Coordinator, U.S. Fish and Wildlife Service, 2140 Eastman Avenue, Suite 100, Ventura, California 93003.

FOR FURTHER INFORMATION CONTACT: Jeff Horwath in the U.S. Fish and Wildlife Service's Division of Fish and Wildlife Management Assistance, Arlington, Virginia at (703) 358–1718. For information about the Alaska marine mammals identified in the **ADDRESSES** Section above, contact Dave McGillivary at (907) 786–3800. For information about West Indian manatees as identified in the **ADDRESSES** Section above, contact Robert Turner at (904) 232–2580. For information about California sea otters and Alaska sea otters in Washington State as identified in the **ADDRESSES** Section above, contact Carl Benz at (805) 644–1766.

SUPPLEMENTARY INFORMATION:

Draft Stock Assessment Reports

On April 30, 1994, the Marine Mammal Protection Act (MMPA) Amendments of 1994 were enacted into public law (Pub. L. 103–238). As amended by new Section 117 of the MMPA, the Service and the NMFS (as appropriate) are required to prepare, and periodically revise, stock assessments for marine mammals that occur in waters under the jurisdiction of the United States. Drafts of these stock assessments were to be completed by August 1, 1994. New Section 117 also requires publication in the **Federal Register** of a notice of availability of the draft stock assessments with a 90-day public review and comment period.

In addition, the NMFS, in consultation with the Service and others, was required to establish by June 30, 1994, three independent regional Scientific Review Groups representing Alaska, the Pacific Coast (including Hawaii), and the Atlantic Coast (including the Gulf of Mexico). These Scientific Review Groups are to provide advice on the stock assessments and other issues appropriate for pursuing the goals of the NMPA. These Groups were established and the Service's draft stock assessments have been provided to them for their review and comment.

Paralleling actions by the NMFS, the Service's draft stock assessments have been divided into the Alaska, Pacific, and Atlantic regions to correspond with the appropriate Scientific Review Group. As specified by the 1944 amendments each stock assessment must, based on the best scientific information available:

(1) Describe the geographic range of the affected stock, including any seasonal or temporal variations in such range;

(2) Provide minimum population estimates, current and maximum net productivity rates, and the current population trend, including a description of the information upon which these are based;

(3) Estimate the annual human-caused mortality and serious injury of the stock by source and, for a strategic stock, other factors that may be causing a decline or impeding recovery of the stock, including effects on marine mammal habitat and prey;

(4) Describe commercial fisheries that interact with the stock, including:

(A) The approximate number of vessels actively participating in each such fishery;

(B) The estimated annual level of incidental mortality and serious injury of the stock by each fishery;

(C) Any seasonal or area differences in such incidental mortality or serious injury; and

(D) The rate, based on the appropriate standard unit of fishing effort, of such incidental mortality and serious injury, and an analysis stating whether such level is insignificant and approaching a zero mortality and serious injury rate.

(5) Categorize the status of the stock as one that either:

(A) Has a level of human-caused mortality and serious injury that is not likely to cause the stock to be reduced below its optimum sustainable population (OSP); or

(B) Is a strategic stock, with a description of the reasons therefor.

(6) Estimate the potential biological removal (PBR) level for the stock describing the information used to calculate it, including the recovery factor.

Congress defined the PBR level as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its OSP level.

Congress defined strategic stocks as those:

(1) For which the level of direct, human-caused mortality exceeds the PBR level;

(2) Which, based on the best available scientific information, are declining and are stocks likely to be listed as threatened under the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531 et seq.) within the foreseeable future; or

(3) Which are listed as threatened or endangered under the ESA or designated as depleted under the MMPA.

The Amendments required the Service to provide, through a notice of availability in the **Federal Register**, a summary of the draft stock assessments and a list of sources of information or published documentation on which each draft assessment is based. To satisfy this requirement and minimize unnecessary duplication, a table that summarizes draft stock assessments appears at the end of this document. The table lists each stock, its regional designation, geographical range, minimum abundance estimate, PBR level, annual estimated average human-caused mortality, and whether or not the stock would be regarded as strategic or nonstrategic.

To maximize the opportunity for full consultation with the Scientific Review Groups, Alaska Native organizations, and the public, the Service is pursuing parallel tracks of review. In addition to the comment period initiated by this notice, the Service began consultation with the Scientific Review Groups by forwarding draft stock assessments on July 29, 1994, to the appropriate Scientific Review Groups for their review and comment. In recognition of the value of traditional Native knowledge and the need for full and equal participation by Alaskan Natives in the decisions that affect the management of marine mammals and, therefore, the subsistence harvest upon which they depend, the Service is seeking direct input from Alaskan Natives, particularly with regard to stocks taken for subsistence. It is important to note that under new Section 117(b)(2) of the MMPA, a formal mechanism is available to Alaskan Natives to require a proceeding on the

record pertaining to the development of a stock assessment prior to its finalization.

At the close of the public comment period, the Service will continue on-going consultation with the Scientific Review Groups by providing the public comments for each draft stock assessment for their additional review and consideration.

PBR Workshop and Reports

Recognizing the need to provide consistent parameters in calculating stock assessments, the NMFS convened a workshop, composed of NMFS and Service scientists, to develop an initial approach for promoting consistent national interpretation of parameters to be used in draft stock assessments, including the calculation of PBR levels, a required component of stock assessments. PBR is calculated as the product of three elements: the minimum population estimate (NMIN); half the maximum net productivity rate (0.5RMAX); and a recovery factor (FA) ranging from 0.1 to 1.0 (i.e., PBR=NMIN×0.5RMAX×FR).

The NMFS convened the workshop to agree on an initial approach for calculating PBR, defining stock structure, and analyzing whether fishery-related incidental mortality and serious injury have reached insignificant levels approaching zero mortality and serious injury rates for use in preparing draft stock assessments. It was the workshop participants' principal objective to identify quantitative criteria for defining input values that could serve as a nationwide standard for calculating PBR.

The workshop participants concluded that the three PBR parameters must be evaluated together, rather than independently, in the context of meeting the goals of the MMPA. In this regard, they concluded that FR should serve to weight the PBR so as to take into account uncertainty in estimates of NMIN, and serve as a "safety factor" that would allow the taking of individuals from stocks below OSP while continuing to promote their recovery and that would provide a safety margin to account for unknown bias in stock status information (e.g., estimation of abundance, productivity, mortality) for stocks of unknown status or trends.

The workshop was held in LaJolla, California, June 27–29, 1994. A copy of the Report of the PBR Workshop is available from the office identified in the **ADDRESSES** Section.

The Service, along with the NMFS, is seeking comments on the methodologies for calculating PBR and other parameters that were agreed to by the workshop participants and employed in the preparation of the draft stock assessments, as well as seeking comments on the individual draft stock assessments.

TABLE OF MARINE MAMMAL DRAFT STOCK ASSESSMENTS FOR FISH AND WILDLIFE SERVICE SPECIES

Marine mammal stock	Regional designation	Geographical range	Minimum population estimate	PBR level[1]	Annual est. avg. human-caused mortality	Strategic or non-strategic
Polar bear:						
Beaufort sea stock	Alaska	Beaufort Sea- Alaska & Canada.	1,778 (S.D.±803).	89	74 Alaska & Canada.	Non-strategic.
Chukchi/Bering Seas stock.	Alaska	Chukchi & Bering Seas- Alaska & Russia.	1,222–3,222	Not determined.	86 Alaska only.	Non-strategic.
Pacific walrus Bering/ Chukchi Seas stock.	Alaska	Alaska & Russia	188,316	5,649	7,500	Strategic.
Sea otter:						
Alaska stock	Alaska	Alaska	100,000	6,000	Not determined.	Non-strategic.
Washington stock	Pacific	Makah Bay to Destruction Island, WA.	307	9	Unknown	Non-strategic.
West Indian Manatee:						
Florida stock	Atlantic	Southeastern U.S.A.	1,856	4	49[2]	Strategic.
Antillean stock	Atlantic	Puerto Rico & U.S. Virgin Islands.	86	0	2	Strategic.
Southern sea otter California stock.	Pacific	Central California & San Nicolas Island.	2,376	Not determined[3].	Unknown	Strategic.

[1] Levels of harvest that are below PBR levels could result in negative impacts to local populations.
[2] Estimated average annual mortality for the West Indian manatee-Florida stock from 1984–1992. The estimated annual mortality from 1974–1992 is 36 animals.
[3] The PBR level for the southern sea otter-California stock was not determined because their incidental take is not governed under Section 118 of the 1994 amendments to the Marine Mammal Protection Act.

Dated: August 15, 1994.

Jay L. Gerst,

Acting Deputy Director, U.S. Fish and Wildlife Service.

[FR Doc. 94–20599 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–55–M

National Park Service

Revision of National Environmental Policy Act Procedures; Request for Comments

AGENCY: National Park Service, Interior.

ACTION: Revision of National Environmental Policy Act Procedures, Request for Comments.

SUMMARY: The National Park Service (NPS) is requesting comments from agencies and the public concerning potential revisions to its procedures under the National Environmental Policy Act (NEPA). When revised such policies would apply to the activities of the National Park Service in administering units of the National Park System as well as other activities. Specifically sought are comments concerning requirements such as time limitations for public and other agency review and comment on potential

environmental effects of NPS actions or other activities affecting NPS resources; what activities should be categorically excluded from the requirements of NEPA; and what activities should normally require preparation of Environmental Impact Statements; and how can integration of the requirements of NEPA be better integrated with other aspects of NPS planning such as General Management Plans, resource management plans and mining plans of operation. The NPS is interested in receiving comments on these and other aspects of its compliance under the NEPA and potential revisions to its existing NEPA policies.

DATES: Comments must be submitted in writing by October 31, 1994.

ADDRESSES: Comments should be sent to: National Park Service, Environmental Quality Division (774), P.O. Box 37127, Washington, D.C. 20013–7127.

FOR FURTHER INFORMATION CONTACT: Jacob J. Hoogland, Chief Environmental Quality Division, National Park Service, Room 1210, 1849 C Street, N.W., Washington, D.C. 20240. Telephone (202) 208–5214.

Denis P. Galvin,

Associate Director, Planning and Development.

[FR Doc. 94–20691 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–70–P

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being consider for listing in the National Register were received by the National Park Service before August 13, 1994. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013–7127. Written comments should be submitted by September 7, 1994.

Antoinette J. Lee,

Acting Chief of Registration, National Register.

Colorado

Weld County

West Stoneham Archeological District, Address Restricted, Stoneham vicinity, 94001115

Georgia

Evans County

Glisson, Remer, Store, GA 129, Fort Stweart Military Reservation, Camp Oliver, 94001090

Walker County

McLemore Cove Historic District, 3 mi. S of Chickamauga, in an area roughly bounded by Lookout and Pigeon Mtns., and GA 136. Kensington vicinity, 94001140

Indiana

Clark County

Abbott-Holloway Farm, Roughly bounded by Second and Walnut Sts., and the Ohio R., Bethlehem. 94001129

Clay County

US Post Office—Brazil, 100 E. National Ave., Brazil. 94001132

Dearborn County

Aurora Methodist Episcopal Church, 304 Third St., Aurora. 94001113

Downtown Aurora Historic District, Bounded by Importing, Water, Market, Fifth, and Exporting Sts., Aurora, 94001134

First Evangelical United Church of Christ, 111 Fifth St., Aurora, 94001104

First Presbyterian Church, 215 Fourth St., Aurora, 94001116

Leive, Parks and Stapp Opera House, 321–325 Second St., Aurora, 94001120

Sutton, Dr. George, Medical Office Building, 315 Third St., Aurora, 94001118

Delaware County

Kitselman, Alva, House, 1400 H. University Ave., Muncie, 94001105

Floyd County

Woodbine, 1800 Old Vincennes Rd., New Albany, 94001107

Hendricks County

Danville Main Street Historic District, Bounded by East, Main, Cross, and Marion Sts., Danville, 94001109

Kellum—Jessup—Chandler Farm, 6726 S. White Lick Creek Rd., Plainfield, 94001111

Randolph County

Farmland Downtown Historic District, Main St. from the alley S of Henry St. to William St., Farmland, 94001124

Ripley County

Tyson United Methodist Church, 324 W. Tyson St., Versailles, 94001106

Wabash County

Hominy Ridge Shelter House, On the S bank of the Salamonie R., N of Hominy Ridge Lake, in the Salamonie River State Forest, Largo, 94001122

Iowa

Black Hawk County

McQuilken, John N. and Mary, House, 602 Commercial St., La Porte City, 94001097

Boone County

Perrigo-Holmes House, 721 Carroll St., Boone, 94001102

Johnson County

Brown Street Historic District (Iowa City MPS). Roughly, Brown St. from W. of Linn St. to Governor St. and adjacent parts of intersecting streets, Iowa City, 94001112

Linn County

Hamilton Brothers Building, 401 First St., SE., Cedar Rapids, 94001098

Lyon County

Broad View Ranch Historic District (Historic Farmsteads of Lyon County MPS), 2572 Log Ave., Sheldon, 94001137

Duncan—Duitsman Farm Historic District (Historic Farmsteads of Lyon County MPS), 4324 180th St., George vicinity, 94001138

Lakewood Farm Historic District (Historic Farmsteads of Lyon County MPS), 2146 Grant Ave., Rock Rapids vicinity, 94001139

Monroe County

White, Arvine and Elizabeth W., House, 309 N. Main St., Albia, 94001100

Page County

Goldenrod Schoolhouse, 1600 S. 16th St., Clarinda, 94001095

Shelby County

Harlan Courthouse Square Commercial District, Market, 6th, 7th, and Court Sts., around Courthouse Sq., Harlan, 94001099

Maryland

Baltimore County

Granite Historic District, Roughly, area surrounding Old Court Rd. and St. Paul Ave., Granite, 94001091

New Hampshire

Belknap County

Busiel, John W., House, 30 Church St., Laconia, 94001094

New Jersey

Camden County

Cattel Tract Historic District, Roughly bounded by N. Chestnut Ave., Cove Rd., Rogers and Leslie Aves., Merchantville, 94001103

Ellis, Col., Joseph, House (Haddon Heights Pre-Revolutionary Houses MPS), 1009 Sycamore St., Haddon Heights, 94001110

Glover, Isaac, House (Haddon Heights Pre-Revolutionary Houses MPS), 1908 New Jersey Ave., Haddon Heights, 94001117

Glover, John Thorn, House (Haddon Heights Pre-Revolutionary Houses MPS), 1212 Sylvan Dr., Haddon Heights, 94001114

Hinchman—Lippincott House (Haddon Heights Pre-Revolutionary Houses MPS), 1089 N. Park Ave., Haddon Heights, 94001121

Mott, Peter, House, Jct. of Moore and Gloucester Aves., Lawnside, 94001101

Hunterdon County

Annandale Historic District, Roughly bounded by Maple Ave., Main St., Beaver Ave. and East St., Clinton Township, Annandale, 94001108

Highfields, End of Lindbergh Rd., East Amwell Township, Amwel vicinity, 94001096

North Carolina

Wake County

Matsumoto House (Early Modern Architecture Associated with NCSU School

of Design Faculty MPS), 821 Runnymeade Rd., Raleigh, 94001089
Paschal House (Early Modern Architecture Associated with NCSU School of Design Faculty MPS), 3334 Almanac Dr., Raleigh, 94001088
Ritcher House (Early Modern Architecture Associated with NCSU School of Design Faculty MPS), 3039 Churchill Rd., Raleigh, 94001087
Small House (Early Modern Architecture Associated with NCSU School of Design Faculty MPS), 310 Lake Boone Trail, Raleigh, 94001086
Small, G. Milton, and Associates, Office Building (Early Modern Architecture Associated with NCSU School of Design Faculty MPS), 105 Brooks Ave., Raleigh, 94001085

Oklahoma

Kay County

First Presbyterian Church of Tonkawa, 109 S. 4th St., Tonkawa, 94001081

Logan County

Guthrie Armory, 720 E. Logan, Guthrie, 94001083
Morris House, 221 Tolson Blvd., Langston, 94001082

Oklahoma County

Edwards, Walter J. and Frances W., House., 1621 N.E. Grand Blvd., Oklahoma City, 94001084

South Carolina

Darlington County

Coker, Robert R., House (Hartsville MPS), 1318 W. Carolina Ave., Hartsville, 94001130
Coker, S. Pressly, House (Hartsville MPS), 402 W. Home Ave., Hartsville, 94001131
Hartsville Armory (Hartsville MPS), 539 W. Carolina Ave., Hartsville, 94001128
Hicks, Wade Hampton, House (Hartsville MPS), 313 W. Home Ave., Hartsville, 94001127
Magnolia Cemetery (Hartsville MPS), S. Cedar Ln., Hartsville, 94001133
McNair, A. M. House (Hartsville MPS), 153 W. Home Ave., Hartsville, 94001126
Rogers, Paul H., House (Hartsville MPS), 628 W. Home Ave., Hartsville, 94001125
West College Avenue Historic District [Hartsville MPS]. W. College Ave. from Sixth Ave. to W of Eighth Ave., Hartsville, 940001123

Tennessee

Knox County

Adair Gardens Historic District [Knoxville and Knox County MPS]. Roughly bounded by Adair, Rose and Coile Drs., Knoxville, 94001136

Texas

Brazori County

GEN. C.B. COMSTOCK (dredge) Shipwreck Site. Address Restricted, Surfside vicinity, 9400119

Virginia

Wythe County

Loretto, 190 Peppers Ferry Rd., Wytheville, 94001093

Roanoke Independent City

Mount Moriah Baptist Church and Cemetery. 3521 E. Orange Ave., Roanoke, 94001092

Wyoming

Fremont County

King, C.H., Company and First National Bank of Shoshoni. 127 Main St., Shoshoni, 94001135

[FR Doc. 94–20654 Filed 8–22–94; 8:45 am]
BILLING CODE 4310–70–M

INTERSTATE COMMERCE COMMISSION

Availability of Environmental Assessments

Pursuant to 42 U.S.C. 4332, the Commission has prepared and made available environmental assessments for the proceedings listed below. Dates environmental assessments are available are listed below for each individual proceeding.

To obtain copies of these environmental assessments contact Ms. Tawanna Glover-Sanders or Ms. Judith Groves, Interstate Commerce Commission, Section of Environmental Analysis, Room 3219, Washington, DC 20423, (202) 927–6203 or (202) 927–6245.

Comments on the following assessment are due 15 days after the date of availability:

AB–333X, UNITY RAILWAYS COMPANY—ABANDONMENT BETWEEN RENTON ROAD AND UNITY JUNCTION IN PLUM BOROUGH, ALLEGHENY COUNTY, PA. EA available 8/16/94.
AB–55 (SUB–NO. 491X), CSX TRANSPORTATION, INC.—ABANDONMENT EXEMPTION—IN POLK COUNTY, FLORIDA. EA available 8/16/94.
AB–1 (SUB–NO. 256X), CHICAGO AND NORTH WESTERN RAILWAY COMPANY—ABANDONMENT EXEMPTION—DES MOINES, POLK COUNTY, IOWA. EA available 8/19/94.
AB–3 (SUB–NO. 118X), MISSOURI PACIFIC RAILROAD COMPANY'S NOTICE OF EXEMPTION FOR DISCONTINUANCE OF TRACKAGE RIGHTS UPON ILLINOIS CENTRAL'S TRACKAGE BETWEEN PINCKNEYVILLE AND PYATTS, IN PERRY COUNTY, ILLINOIS. EA available 8/19/94.
AB–43 (SUB–NO. 164X), ILLINOIS CENTRAL RAILROAD COMPANY—NOTICE OF EXEMPTION UNDER 49 C.F.R. § 1152.50—ABANDONMENT OF LINE IN PERRY COUNTY, ILLINOIS. EA available 8/19/94.

Comments on the following assessment are due 30 days after the date of availability:

AB–55 (SUB–NO. 490X), CSX TRANSPORTATION, INC.—ABANDONMENT IN PULASKI COUNTY, INDIANA. EA available 8/19/94.

Vernon A. Williams,
Acting Secretary.

[FR Doc. 94–20652 Filed 8–22–94; 8:45 am]
BILLING CODE 7035–01–P

[Docket No. AB–290 (Sub–No. 144X)]

Norfolk Southern Railway Company—Abandonment Exemption—Jefferson County, AL

Norfolk Southern Railway Company (NS) has filed a notice of exemption under 49 CFR 1152 Subpart F—Exempt Abandonments to abandon its 2.2-mile line of railroad extending between NS milepost 35.0–R, at Burstall, and milepost 37.2–R, at Valley Creek Junction, both in Jefferson County, AL.

NS has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (service of environmental report on agencies), 49 CFR 1105.8 (service of historic report on State Historic Preservation Officer), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 22, 1994, unless stayed pending reconsideration. Petitions to

stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29[3] must be filed by September 2, 1994. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by September 12, 1994, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Robert J. Cooney, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510–2191.

If the notice of exemption contains false or misleading information, the use of the exemption is void ab initio.

Applicant has filed an environmental report which addresses the abandonment's effects, if any, on the environmental and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by August 26, 1994. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA is available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: August 15, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Acting Secretary.

[FR Doc. 94–20649 Filed 8–22–94; 8:45 am]

BILLING CODE 7035–01–P

[1] A stay will be issued routinely by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Environmental Analysis in its independent investigation) cannot be made before the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

[Finance Docket No. 32543]

SEMO Port Railroad, Inc.—Acquisition and Operation Exemption—Certain Lines of Missouri Pacific Railroad Company

SEMO Port Railroad, Inc. (SEMO), a noncarrier subsidiary of Southeast Missouri Regional Port Authority, has filed a notice of exemption to acquire and operate approximately 5.53 miles of rail line owned by the Missouri Pacific Railroad Company (MP) between approximately milepost 122.98 at Capedeau Junction and approximately milepost 128.51 at Rush Junction, in the City of Cape Girardeau, MO. The parties intended to consummate the transaction on or after August 1, 1994.[1]

Any comments must be filed with the Commission and served on: Kevin M. Sheys, 1020 19th Street, NW., Suite 400, Washington, DC 20036.

This notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: August 15, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Acting Secretary.

[FR Doc. 94–20651 Filed 8–22–94; 8:45 am]

BILLING CODE 7035–01–P

[1] Under 49 CFR 1150.32(b), an exemption does not become effective until 7 days after the notice is filed. Here, the notice of exemption was not filed until August 1, 1994, and thus the exemption was not effective until August 8, 1994. Petitioner's representative has confirmed that the correct consummation date is on or after August 8, 1994.

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

In accordance with Departmental policy, 28 CFR § 50.7, notice is hereby given that a proposed consent decree in *United States* v. *AT&T, et al.*, Civil Action No. 2:94CV00438, was lodged on August 3, 1994, with the United States District Court for the Middle District of North Carolina. This agreement resolves a judicial enforcement action brought by the United States against the defendants pursuant to Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act of 1986, Pub. L. 99–499, 42 U.S.C. §§ 9606 and 9607, for the cleanup of the Bypass 601 Superfund Site ("Site") in Cabarrus County, Concord, North Carolina, and for the recovery of response costs incurred and to be incurred by the United States in connection with the Site.

The consent decree requires the settling defendants to pay 100 percent of the past and future response costs which the United States has incurred and will incur at the Site. The settling defendants have also agreed under the decree to perform the final remedy for the Site which EPA set forth in its Record of Decision dated April 20, 1993, and which provides for excavation, treatment, and on-site disposal of contaminated soils, and extraction and treatment of contaminated groundwater across the Site.

The settling defendants have also covenanted not to sue other potentially responsible parties who sent less than 320 pounds of lead-bearing materials to the Site. The United States has agreed under this Decree to provide up to $10.1 million in preauthorized mixed funding pursuant to Section 122(b)(1) of CERCLA, 42 U.S.C. § 9622(b)(1). This Decree has been executed in conjunction with an Administrative Order on Consent whereby a group of potentially responsible parties who sent less than 40,000 pounds of lead-bearing materials to the Site will each pay a portion of the past costs.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *AT&T, et al.*, DOJ Ref. #90–11–3–1128.

The proposed consent decree may be examined at the Office of the United States Attorney, 324 West Market Street, Greensboro, North Carolina 27402; at the Region IV Office of the Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365; and at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005, 202–624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $80.75 (25

cents per page reproduction costs), payable to the Consent Decree Library.

John C. Cruden,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 94–20577 Filed 8–22–94; 8:45 am]

BILLING CODE 4410–01–M

Immigration and Naturalization Service

[INS No. 1667–94; AG Order No. 1911–94]

RIN 1115–AC30

Extension of Designation of Somalia Under Temporary Protected Status Program

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice.

SUMMARY: This notice extends, until September 17, 1995, the Attorney General's designation of Somalia under the Temporary Protected Status program provided for in section 244A of the Immigration and Nationality Act, as amended ("the Act"). Accordingly, eligible aliens who are nationals of Somalia, or who have no nationality and who last habitually resided in Somalia, may re-register for Temporary Protected Status and extension of employment authorization. This re-registration is limited to persons who already registered for the initial period of Temporary Protected Status, which ended on September 16, 1992. In addition during the extension period, some aliens may be eligible for late initial registration pursuant to 8 CFR 240.2(f)(2).

EFFECTIVE DATES: This extension of designation is effective on September 18, 1994, and will remain in effect until September 17, 1995. Re-registration procedures become effective on August 23, 1994, and will remain in effect until September 22, 1994.

FOR FURTHER INFORMATION CONTACT: Ronald Chirlin, Senior Immigration Examiner, Immigration and Naturalization Service, Room 3214, 425 I Street NW., Washington, DC 20536, telephone (202) 514–5014.

SUPPLEMENTARY INFORMATION: Under section 244A of the Act, as amended by section 302(a) of Pub. L. 101–649 and section 304(b) of Pub. L. 102–232 (8 U.S.C. 1254a), the Attorney General is authorized to grant Temporary Protected Status in the United States to eligible aliens who are nationals of a foreign state designated by the Attorney General, or who have no nationality and who last habitually resided in that state. The Attorney General may designate a state, or a part thereof, upon finding that the state is experiencing ongoing armed conflict, environmental disaster, or certain other extraordinary and temporary conditions that prevent nationals or residents of the country from returning in safety.

Effective on September 16, 1991, the Attorney General designated Somalia for Temporary Protected Status for a period of one year, 56 FR 46804. The Attorney General extended the designation of Somalia under Temporary Protected Status program for additional one-year periods until September 17, 1993, 57 FR 32232, and until September 17, 1994, 58 FR 48898.

This notice extends the designation of Somalia under the Temporary Protected Status program for an additional year, in accordance with sections 244A(b)(3) (A) and (C) of the Act. This notice also describes the procedures with which eligible aliens who are nationals of Somalia, or who have no nationality and who last habitually resided in Somalia, must comply in applying for continuation of Temporary Protected Status.

In addition to timely re-registrations and late re-registrations authorized by this notice's extension of Somalia's Temporary Protected Status designation, late initial registrations are possible for some Somalis under 8 CFR 240.2(f)(2). Such late initial registrants must have been continuously physically present in the United States since September 16, 1991, and must have had a valid immigrant or non-immigrant status during the original registration period. For each Application for Temporary Protected Status, Form I–821, filed for late initial registration, a fee of fifty dollars ($50) is charged. An Application for Employment Authorization, Form I–765, must be filed together with Form I–821 in all cases. However, the fee prescribed in 8 CFR 103.7(b)(1) for Form I–765 is only charged if the alien requests employment authorization.

The general fee for filing an Application for Employment Authorization, Form I–765, was increased to seventy dollars ($70) on July 14, 1994. (See 59 FR 30516.) The new fee is required when Form I–765 is filed as part of either a re-registration or as part of a late initial registration for Temporary Protected Status. This filing fee must accompany Form I–765 unless a properly documented fee waiver request is submitted to the Immigration and Naturalization Service or the applicant does not request employment authorization.

Notice of Extension of Designation of Somalia Under Temporary Protected Status Program

By the authority vested in me as Attorney General under section 244A of the Immigration and Nationality Act, as amended, and pursuant to sections 244A(b)(3) (A) and (C) of the Act, I have determined that, as a result of the ongoing civil unrest in Somalia, there still exist extraordinary and temporary conditions in that country that prevent aliens who are nationals of Somalia, and aliens having no nationality who last habitually resided in Somalia, from returning to Somalia in safety. I have further determined that permitting nationals of Somalia, and aliens having no nationality who last habitually resided in Somalia, to remain temporarily in the United States is not contrary to the national interest of the United States. Accordingly, it is ordered as follows:

(1) The designation of Somalia under section 244A(b) of the Act is extended for an additional one-year period from September 18, 1994, to September 17, 1995.

(2) I estimate that there are approximately 350 nationals of Somalia, and aliens having no nationality who last habitually resided in Somalia, who have been granted Temporary Protected Status and who are eligible for re-registration.

(3) A national of Somalia, or an alien having no nationality who last habitually resided in Somalia, who received a grant of Temporary Protected Status during the initial period of designation from September 16, 1991, to September 16, 1992, must comply with the re-registration requirements contained in 8 CFR 240.17, which are described in pertinent part in paragraphs (4) and (5) of this notice.

(4) A national of Somalia, or an alien having no nationality who last habitually resided in Somalia, who previously has been granted Temporary Protected Status, must re-register by filing a new Application for Temporary Protected Status, Form I–821, together with an Application for Employment Authorization, Form I–765, within the 30-day period beginning on August 23, 1994 and ending on September 22, 1994 in order to be eligible for Temporary Protected Status during the period from September 18, 1994, until September 17 1995. Late re-registration applications will be allowed for "good cause" pursuant to 8 CFR 240.17(c).

(5) There is no fee for the Form I–821 filed as part of the re-registration application. The fee prescribed in 8 CFR 103.7(b)(1) will be charged for the Form

I–765, filed by an alien requesting employment authorization pursuant to the provisions of paragraph (4) of this notice. An alien who does not request employment authorization must file Form I–821 together with Form I–765 for informational purposes, but in such cases both Form I–821 and Form I–765 may be submitted without fee.

(6) Pursuant to section 244A(b)(3)(A) of the Act, the Attorney General will review, at least 60 days before September 17, 1995, the designation of Somalia under the Temporary Protected Status program to determine whether the conditions for designation continue to exist. Notice of that determination, including the basis for the determination, will be published in the **Federal Register**.

(7) Information concerning the Temporary Protected Status program for nationals of Somalia, and aliens having no nationality who last habitually resided in Somalia, will be available at local Immigration and Naturalization Service offices upon publication of this notice.

Dated: August 15, 1994.

Janet Reno,

Attorney General.

[FR Doc. 94–20573 Filed 8–22–94; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

Background: The Department of Labor, in carrying out its responsibilities under the Paperwork Reduction Act (44 U.S.C. Chapter 35), considers comments on the reporting/recordkeeping requirements that will affect the public.

List of Recordkeeping/Reporting Requirements Under Review: As necessary, the Department of Labor will publish a list of the Agency recordkeeping/reporting requirements under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Officer will, upon request, be able to advise members of the public of the nature of the particular submission they are interested in.

Each entry may contain the following information:

The Agency of the Department issuing this recordkeeping/reporting requirement.

The title of the recordkeeping/reporting requirement.

The OMB and/or Agency identification numbers, if applicable.

How often the recordkeeping/reporting requirement is needed.

Whether small businesses or organizations are affected.

An estimate of the total number of hours needed to comply with the recordkeeping/reporting requirements and the average hours per respondent.

The number of forms in the request for approval, if applicable.

An abstract describing the need for and uses of the information collection.

Comments and Questions: Copies of the recordkeeping/reporting requirements may be obtained by calling the Departmental Clearance Officer, Kenneth A. Mills (202) 219–5095. Comments and questions about the items on this list should be directed to Mr. Mills, Office of Information Resources Management Policy, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–1301, Washington, DC 20210. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OAW/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 3001, Washington, DC 20503 (202) 395–7316.

Any member of the public who wants to comment on recordkeeping/reporting requirements which have been submitted to OMB should advise Mr. Mills of this intent at the earliest possible date.

New

Employment and Training Administration

Evaluation of the Impacts of the Job Corps Program on Participant's Postprogram Labor Market and Related Behaviors

On Occasion

Individuals or households; State or local governments; Federal agencies or employees

Form No.	Respondents	Average time per response
Sampling Form:		
JC Screener	90,019	2 minutes.
JC Applicant	90,019	4 minutes.
Consent Form	90,019	2 minutes.
Baseline Survey ..	15,092	40 minutes.
22,084 total hours		

This study will measure Job Corps impacts on participant's employment and related behavior, and assess the program's cost effectiveness. Congress and the Department will use the study to guide training policy decisions. Program applicants, recruiters, and center operators will be affected by this study.

Signed at Washington, DC this 18th day of August, 1994.

Theresa M. O'Malley,

Acting Departmental Clearance Officer.

[FR Doc. 94–20646 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

Commission on the Future of Worker-Management Relations; Notice of Meeting

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of public meeting.

SUMMARY: The Commission on the Future of Worker-Management Relations was established in accordance with the Federal Advisory Committee Act (FACA) Pub. L. 92–463. Pursuant to Section 10(a) of FACA, this is to announce that the Commission will meet at the time and place show below.

TIME AND PLACE: The meeting will be held on Thursday, September 8, 1994 from 9:00 a.m. to 3:00 p.m. in Conference Room N–3437 A–D in the Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

AGENDA The agenda for the meeting is as follows:

The Commission is seeking proposals and options to deal with problems, such as those identified in its Fact Finding Report, related to issues of the present legal framework and practices of collective bargaining to enhance cooperative behavior, improve productivity and reduce conflict and delay.

The Commission invites the views of interested parties about the problems that are reported to arise under the current law and the recommendations they would make to deal with these problems.

PUBLIC PARTICIPATION: The Commission will be in session and open to the public from 9:00 a.m. until 3:00 p.m. when it will adjourn. Seating will be available on a first-come, first-served basis. Individuals with disabilities wishing to attend, should contact the Commission to request appropriate accommodations. Individuals or organizations wishing to submit written statements should send 15 copies on or before September 2 to Mrs. June M. Robinson, Designated Federal Official, Commission on the Future of Worker-Management Relations, U.S. Department of Labor, 200 Constitution Avenue, NW.,

Washington, DC 20210, telephone (202) 219–9148.

Signed at Washington, DC this 18th day of August 1994.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 94–20647 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–23–M

Employment and Training Administration

[TA–W–29,162 and TA–W–29,162A]

Alaska Pulp Corp., Sitka Pulp Mill, Sitka, AK and Rowan Bay Logging, Sitka, AK; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 27, 1994, applicable to all workers of the subject firm. The certification notice was published in the **Federal Register** on February 14, 1994 (59 FR 6964).

As a result of a NAFTA petition (NAFTA 00185) for workers at Rowan Bay Logging of the Alaska Pulp Corporation in Sitka, Alaska, the Department reviewed the subject certification for workers of the Sitka Pulp Mill of the Alaska Pulp Corporation.

New findings indicate show that the Alaska Pulp Corporation owns Rowan Bay Logging. Rowan Bay Logging ships its logs to the Sitka Pulp Mill whose workers were issued the instant certification on January 27, 1994. Other findings show that Rowan Bay Logging had substantial worker separations in mid-1994 and that logging operations were reduced because of the reduced activity at the pulp mill.

The intent of the Department's certification is to include all workers who were adversely affected by increased imports. Accordingly, the Department is amending the certification to show the Rowan Bay Logging.

The amended notice applicable to TA–W–29,162 is hereby issued as follows:

All workers of the Alaska Pulp Corporation, Sitka Pulp Mill, Sitka, Alaska and Rowan Bay Logging, Sitka, Alaska who became totally or partially separated from employment on or after October 15, 1992 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this August 12, 1994.

James D. Van Erden,

Administrator, Office of Work-Based Learning.

[FR Doc. 94–20644 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–29,105 and TA–W–29,105A]

Custom Resins Division, Bemis Company, Inc., Henderson, KY and Suffield, CT; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 14, 1994, applicable to all workers of Custom Resins Division of Bemis Company, Inc., Henderson, Kentucky. The Notice was published in the **Federal Register** on February 3, 1994 (59 FR 5213).

At the request of the State Agency, The Department reviewed the certification for the workers of the subject firm. New findings show that the Suffield, Connecticut sales office was closed in 1994. All sales workers were on the salaried payroll of Bemis Company, Inc.

The intent of the Department's certification is to include all workers of the Custom Resins Division of Bemis Company, Inc., who were affected by increased imports of polymer resins.

The amended notice applicable to TA–W–29,105 is hereby issued as follows:

All workers of Customs Resins Division of Bemis Company, Inc., Henderson, Kentucky and Suffield, Connecticut who were engaged in the employment related to the production of polymer resins who became totally or partially separated from employment on or after September 29, 1992 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 12th day of August, 1994.

Violet L. Thompson,

Deputy Director, Office of Trade Adjustment Assistance.

[FR Doc. 94–20643 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–27,584, etc.]

Fina Oil and Chemical Company—Exploration and Production Group; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In the matter of TA–W–27,548 Headquarters-Dallas, Texas, TA–W–27,549 South Louisiana Division-Houston, Texas, TA–W–27,549A Texas, except Houston, TA–W–27,549B Louisiana, TA–W–27,550 South Texas Division-Houston, Texas, TA–W–27,550A Texas, except Houston, TA–W–27,550B Louisiana, TA–W–27,551 East Texas Division-Tyler, Texas, TA–W–27,551A Texas, except Tyler, TA–W–27,551B Louisiana, TA–W–27,581 West Texas Division-Midland, Texas, TA–W–27,581A Texas, except Midland, TA–W–27,581B Louisiana, TA–W–27,582 Offshore Division-Houston, Texas, TA–W–27,582A Alabama, TA–W–27,582B Colorado, TA–W–27,582C Oklahoma, TA–W–27,582D Texas, except Houston, and TA–W–27,582E Louisiana.

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 2, 1992, applicable to all workers of the above mentioned locations of Fina Oil and Chemical Company, Exploration and Production Group.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. Several workers were laid off in other parts of Texas and Louisiana for the above cited divisions of Fina Oil and Chemical Company, Exploration and Production Group.

Accordingly, the Department is amending the certification to include all workers in the above cited divisions in Louisiana, Texas, Alabama, Colorado and Oklahoma.

The amended notice applicable to TA–W–27,548, through TA–W–27,551 and TA–W–27,581 and TA–W–27,582 are hereby issued as follows:

All workers at the following locations of the Exploration and Production Group of Fina Oil and Chemical Company: (1) TA–W–27,548 Headquarters, Dallas, Texas; (2) TA–W–27,549 South Louisiana Division, Houston, Texas, Texas except Houston, Louisiana; (3) TA–W–27,550 South Texas Division, Houston, Texas, Texas except Houston, Louisiana; (4) TA–W–27,551 East Texas Division, Tyler, Texas, Texas, except Tyler, Louisiana; (5) TA–W–27,581 West Texas Division, Midland, Texas, Texas except Midland, Louisiana; (6) TA–W–27,582 Offshore Division, Houston, Texas, Alabama, Colorado, Oklahoma, Texas, except Houston and Louisiana who became totally or partially separated from employment on or after July 22, 1991 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 12th day of August, 1994.

Violet L. Thompson,

Deputy Director, Office of Trade Adjustment Assistance.

[FR Doc. 94–20645 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

[TA-W-29,574]

Martin Marietta Magnesia Specialties, Inc., Manistee, MI; Notice of Revised Determination on Reconsideration

On July 19, 1994, the Department issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of the subject firm. The affirmative notice regarding application was published in the **Federal Register** on July 28, 1994 (59 FR 38493–4).

The workers produce magnesia refractories for use in industrial applications primarily for steel. Workers separations occurred in 1993 and 1994.

On reconsideration the company submitted additional data for the first six months of 1994. The new data shows sales of refractories decreased in the first six months of 1994 compared to the same period in 1993.

Other findings show company imports of refractories increased in the first six months of 1994 compared to the same period of 1993 and accounted for a substantial portion of Martin Marietta Magnesia Specialties' 1994 sales.

Conclusion

After careful consideration of the new facts obtained on reconsideration, it is concluded that Martin Marietta Magnesia Specialties' workers in Manistee, Michigan were adversely affected by increased imports of articles like or directly competitive with the magnesia refractories produced at Martin Marietta Magnesia Specialties in Manistee, Michigan.

All workers of Martin Marietta Magnesia Specialties, Inc. in Manistee, Michigan who became totally or partially separated from employment on or after February 15, 1993 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 11th day of August 1994.

James D. Van Erden,

Administrator, Office of Work-Based Learning.

[FR Doc. 94–20642 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA–00120]

Walker Manufacturing Co., Hebron, OH; Notice of Affirmative Determination Regarding Application for Reconsideration

On July 29, 1994, the United Auto Workers (UAW) requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for NAFTA-Transitional Adjustment Assistance for workers at the subject firm. The Department's Negative Determination was issued on June 30, 1994 and was published in the **Federal Register** on July 26, 1994 (59 FR 37997).

The union submitted data regarding assets sent to Mexico for the production of mufflers. The union also claims that the Department's survey was inadequate.

Conclusion

After careful review of the application, I conclude that the claims are of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 12th day of August 1994.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, Unemployment Insurance Service.

[FR Doc. 94–20641 Filed 8–22–94; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Challenge and Advancement Advisory Panel; Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Challenge and Advancement Advisory Panel (Arts in Education Section) to the National Council on the Arts will be held on September 23, 1994. The panel meeting from 10:00 a.m. to 4:30 p.m. in Room 730, at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public from 3:45 p.m. to 4:30 p.m. for a policy discussion.

Remaining portion of this meeting from 10:00 a.m. to 3:45 p.m. is for the purpose of panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of February 8, 1994, this session will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the Panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, N.W., Washington, D.C., 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Committee Management Officer, National Endowment for the Arts, Washington, D.C., 20506, or call 202/682–5439.

Dated: August 17, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–20583 Filed 8–22–94; 8:45 am]

BILLING CODE 7537–01–M

Challenge and Advancement Advisory Panel; Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a metting of the Challenge and Advancement Advisory Panel (Design Arts Section) to the National Council on the Arts will be held on September 12, 1994. The panel will meet from 10:00 a.m. to 4:00 p.m. in Room M–14, at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC 20506.

A portion of this meeting will be open to the public from 3:30 p.m. to 4:00 p.m. for a policy discussion.

Remaining portion of this meeting from 10:30 a.m. to 3:30 p.m. is for the purpose of panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of February 8, 1994, this session will be closed to the public pursuant to subsection (c) (4), (6) and (9)(B) of Section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the Panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Committee Management Office, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: August 17, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–20582 Filed 8–22–94; 8:45 am]

BILLING CODE 7537–01–M

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel with be held at the Old Post Office, 1100 Pennsylvania Avenue NW., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* September 7, 1994.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in Teacher-Scholar Program, submitted to the Division of Education Programs, for projects beginning after December 1, 1994.

2. *Date:* September 9, 1994.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in Teacher-Scholar Program, submitted to the Education Programs, for projects beginning after December 1, 1994.

3. *Date:* September 12, 1994.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications in Library and Archival Preservation and Access Projects, submitted to the Division of Preservation and Access, for projects beginning after January 1, 1995.

4. *Date:* September 13, 1994.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in the Teacher-Scholar Program, submitted to the Division of Education Programs, for projects beginning after December 1, 1994.

5. *Date:* September 15, 1994.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in the Teacher-Scholar Program, submitted to the Division of Education Programs, for projects after December 1, 1994.

6. *Date:* September 16, 1994.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications in Library and Archival Preservation and Access Projects, submitted to the Division of Preservation and Access, for projects beginning after January 1, 1995.

7. *Date:* September 19, 1994.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications in Library and Archival Preservation and Access Projects, submitted to the Division of Preservation and Access, for projects beginning after January 1, 1995.

8. *Date:* September 20, 1994.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in the Teacher-Scholar Program, submitted to the Division of Education Programs, for projects beginning after December 1, 1994.

9. *Date:* September 23, 1994.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications in Library and Archival Preservation and Access Projects, submitted to the Division of Preservation and Access, for projects beginning after January 1, 1995.

10. *Date:* September 30, 1994.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications in Library and Archival Preservation and Access Projects, submitted to the Division of Preservation and Access, for projects beginning after January 1, 1995.

David Fisher,

Advisory Committee, Management Officer.

[FR Doc. 94–20619 Filed 8–22–94; 8:45 am]

BILLING CODE 7536–01–M

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (P.L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, P.L. 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to these permit applications by September 19, 1994. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 306–1031.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Public Law 95–541), has

developed regulations that implement the "Agreed Measures for the Conservation of Antarctic Fauna and Flora" for all United States citizens. The Agreed Measures, developed by the Antarctic Treaty Consultative Parties, recommended establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Specially Protected Areas and Sites of Special Scientific Interest.

The applications received are as follows:

1. *Applicant*

Brenda Hall
Institute for Quaternary Studies
320 Boardman Hall
University of Maine
Orono, Maine 04469–5711

Activity for Which Permit Is Requested

Enter Site of Special Scientific Interest

The applicant is in the process of carrying out a large mapping project to determine the former extent of a grounded ice sheet in the Ross Sea during the last glaciation. Much of the work has been concentrated on the Dry Valleys region where lobes of the grounded Ross Sea Ice Sheet flowed inland into the mouths of the valleys. Barwick Valley (SSSI #3) was last mapped in the 1960's. According to that work, inland ice advanced down Barwick Valley simultaneously with the ice advance into the Lower Victoria Valley from the Ross Sea. The Lower Victoria Valley deposits indicate the presence of a lake, not an ice tone. A revised map of Barwick Valley would help determine the extend of the lake in the Victoria Valley System and to examine evidence of lake-level fluctuations. The applicant plans only to map Barwick Valley. no samples will be taken. Access to the site will be on foot from the Victoria Valley where the majority of the project will be conducted.

Location

SSSI #3—Barwick Valley, Victoria Land, Antarctica

Dates

November 1, 1994—February 15, 1995

2. *Applicant*

George Denton and David Marchant
Institute for Quaternary Studies
320 Boardman Hall
University of Maine
Orono, Maine 04469–5711

Acitivity for Which Permit Is Requested

Enter Site of Special Scientific Interest

The applicants are in the process of carrying out a large mapping project to determine the former extent of a grounded ice sheet in the Ross Sea approximately 22,000–8,000 years ago. Ross Island is a key area for this study as the island was a nunatak project through the ice sheet. Cape Crozier (SSSI #4) is open for the few ice-free areas on the island and the only ice-free area on the eastern coast. Mapping the glacial geology of this area to determine the elevation of the former ice sheet and gain information about ice-flow directions is critical to the project. The applicants only plan to map the area. No rocks or soil samples will be collected and they will be working at elevations above the penguin rookery and at least a mile away at all times. Access to the site will be by helicopter.

Location

SSSI #4—Cape Crozier, Ross Island, Antarctica

Dates

October 1, 1994—March 1, 1995

Nadene G. Kennedy,

Permit Office, Office of Polar Programs.

[FR Doc. 94–20574 Filed 8–22–94; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL TRANSPORTATION SAFETY BOARD

Public Hearing in Charlotte, NC: Aviation Accident

In connection with the investigation of the USAir Flight 1016, Douglas DC-9-30, accident at Charlotte, North Carolina, July 2, 1994, the National Transportation Safety Board will convene a public hearing at 12:00 p.m. (eastern standard time), on Monday, September 19, 1994, in the Grand Ballroom of the Charlotte Marriott Executive Park Hotel, 5700 Westpark Drive, Charlotte, North Carolina. For more information, contact Alan Pollock, Office of Public Affairs, National Transportation Safety Board, 490 L'Enfant Plaza, SW., Washington, D.C. 20594, telephone (202) 382–0660.

Dated: August 18, 1994.

Bea Hardesty,

Federal Register Liaison Officer.

[FR Doc. 94–20630 Filed 8–22–94; 8:45 am]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

Proposed Generic Communication; "Voltage-Based Repair Criteria for the Repair of Westinghouse Steam Generator Tubes Affected by Outside Diameter Stress Corrosion Cracking; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of opportunity for public comment, correction.

SUMMARY: This document corrects a general notice that appeared in the **Federal Register** of August 12, 1994 (59 FR 41520), that presents a draft generic letter to all holders of operating licenses or construction permits for nuclear power reactors having steam generators designed by Westinghouse Electric Corporation for public comment. This action is necessary to correct an erroneous telephone number.

On page 41521, in the third column under the For Further Information Contact heading, the telephone number for Timothy A. Reed should be corrected to read 504–1462.

Dated at Rockville, Maryland, this 16th day of August 1994.

For the Nuclear Regulatory Commission.

Elizabeth L. Doolittle,

Acting Chief, Generic Communications Branch, Division of Operating Reactor Support, Office of Nuclear Reactor Regulation.

[FR Doc. 94–20617 Filed 8–22–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–213]

Connecticut Yankee Atomic Power Co.; Notice of Issuance of Amendment to Facility Operation License

The U.S. Nuclear Regulatory Commission (Commission) has issued Amendment No. 175 to Facility Operating License No. DPR–61 issued to the Connecticut Yankee Atomic Power Company (the licensee), which revised the Technical Specifications for operation of the Haddam Neck Plant located in Middlesex County, Connecticut. The amendment is effective as of the date of issuance to be implemented within 30 days of issuance.

The amendment revises the Haddam Neck Plant Technical Specifications (TS) to allow an increased limit for fuel enrichment. The change allows the storage of fuel with an enrichment not to exceed a nominal 5.0 weight percent (w/o) U–235 in the Haddam Neck Plant new and spent fuel storage racks. The

current new and spent fuel storage rack maximum nominal enrichment is 3.9 w/o U–235 for Zircaloy clad fuel and 4.0 w/o U–235 for stainless steel clad fuel.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the **Federal Register** on February 8, 1994 (59 FR 5788). No request for a hearing or petition for leave to intervene was filed following the notice.

The Commission has prepared an Environmental Assessment related to the action and has determined not to prepare an environmental impact statement. Based upon the environmental assessment, the Commission has concluded that the issuance of the amendment will not have a significant effect on the quality of the human environment (59 FR 40926).

For further details with respect to the action see (1) the application for amendment dated January 6, 1994, as supplemented March 16, 1994, (2) Amendment No. 175 to License No. DPR–61, (3) the Commission's related Safety Evaluation, and (4) the Commission's Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555, and at the local public document room located at the Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Dated at Rockville, Maryland, this 16th day of August 1994.

For the Nuclear Regulatory Commission.

Alan B. Wang,

Project Manager, Project Directorate I–4, Division of Reactor Projects–I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 94–20616 Filed 8–22–94; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Federal Employees Health Benefits Program Medically Underserved Areas for 1995

AGENCY: Office of Personnel Management.

ACTION: Notice of medically underserved areas for 1995.

SUMMARY: The Office of Personnel Management has completed its annual determination of the States that qualify as Medically Underserved Areas under the Federal Employees Health Benefits (FEHB) Program for calendar year 1995. This determination is necessary to comply with a provision of FEHB law that mandates special consideration for enrollees of certain FEHB plans who receive covered health services in States with critical shortages of primary care physicians. Accordingly, for calendar year 1995, OPM has determined that the following States are Medically Underserved Areas under the FEHB Program: Alabama, Georgia, Louisiana, Mississippi, New Mexico, North Dakota, South Carolina, South Dakota, West Virginia, and Wyoming. This list is the same as that for 1994, with the exception of the addition of Georgia.

EFFECTIVE DATE: January 1, 1995.

FOR FURTHER INFORMATION CONTACT: KAREN LEIBACH, (202) 606–0191.

SUPPLEMENTARY INFORMATION: FEHB law [5 U.S.C. 8902(m)(2)] mandates special consideration for enrollees of certain FEHB plans who receive covered health services in States with critical shortages of primary care physicians. Such States are designated as Medically Underserved Areas for purposes of the FEHB Program, and the law requires payment to all qualified providers in these States.

FEHB regulations (5 CFR 890.701) require OPM to make an annual determination of the States that qualify as Medically Underserved Areas for the next calendar year by comparing the latest Department of Health and Human Services State-by-State population counts on primary medical care manpower shortage areas with U.S. Census figures on State resident population.

U.S. Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

[FR Doc. 94–20521 Filed 8–22–94; 8:45 am]

BILLING CODE 6325–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–34529; File No. SR–GSCC–94–04]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Notice of Filing of Proposed Rule Change Establishing New Categories of Netting System Membership for Futures Commission Merchants

August 12, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on July 5, 1994, the Government Securities Clearing Corporation ("GSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–GSCC–94–04) as described in Items I, II, and III below, which Items have been prepared primarily by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change will establish new categories of netting system membership for futures commission merchants ("FCMs").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

GSCC was established primarily to provide the government securities marketplace with risk protections and a means of ensuring orderly settlement. The initial set of market participants for which it was intended GSCC provide its netting and risk protection services were large dealers and interdealer brokers.

[1] 15 U.S.C. § 78s(b)(1) (1988).

Nevertheless, it was recognized at the time GSCC was established and was made a prerequisite by the Commission for permanent registration that GSCC's netting system ultimately was not to be solely for the benefit of the primary dealer community and that additional classes of market participants would be encompassed as members in the future.

After consideration of the matter following expressions of interest in netting system membership by several FCMs, GSCC has determined it appropriate to establish a Category 1 FCM netting system membership class and a Category 2 FCM netting system membership class.[2]

FCMs

Typically, an FCM is an entity that solicits orders, accepts orders, and/or accepts funds for the purchase or sale of exchange traded options on futures or futures. In effect, an FCM is the equivalent in the futures industry of a securities broker.

With certain limited exceptions, any person who acts as an FCM must register as such with the Commodity Futures Trading Commission ("CFTC"). Once registered, the FCM must comply with the CFTC's rules on pre-account opening and transactional disclosure, various trading proscriptions, customer account supervision, minimum net capital, segregation and protection of customer funds, recordkeeping, and reporting.

Most FCMs also are members of one or more futures exchanges and therefore are subject to futures exchange regulation and oversight. If an FCM is a member of a futures exchange or a registered futures association it will be audited by a designated organization to assure compliance with their capital requirements. In addition, FCMs that desire to clear their own trades on a particular exchange become clearing members of that futures exchange or its clearing affiliate. Clearing membership subjects the FCM to additional rules and to closer oversight from a financial perspective.

Proposed Minimum Financial Standards

The term "net capital" as used in GSCC's rules and the Commission's net capital rule is the approximate accounting equivalent of the term "adjusted net capital" as that term is used in the CFTC financial requirement rule. In addition, the term "net worth" as used in GSCC's rules is comparable to the concept of "net worth" in the CFTC's financial requirement rule.

Given these similarities, GSCC believes there is a basis for establishing categories of FCM netting membership with minimum financial standards and margin requirements that are equivalent to those for Category 1 and Category 2 dealer netting members. Specifically, GSCC will establish a Category 1 FCM with minimum financial standards of $50 million in net worth and $10 million in excess adjusted net capital and a clearing fund requirement the same as a Category 1 dealer netting member. A Category 2 FCM will be established with minimum financial standards of $25 million in net worth and $10 million in excess adjusted net capital and a clearing fund requirement the same as for Category 2 dealer netting members.

While dealer netting members are required to file regulatory financial reports on a monthly basis, the CFTC requires all FCMs, except introducing brokers, as of the close of business each month only to make and to keep a record of their computation of adjusted net capital. In view of this, GSCC will require every FCM netting member to furnish GSCC each month with a copy of the computation of adjusted net capital required by the CFTC in addition to furnishing to GSCC a copy of the CFTC's regulatory financial report at the time that the form is filed with the CFTC each quarter.

GSCC believes that because the proposed rule change allows GSCC to broaden access to its netting and risk management services thereby allowing a greater number of market participants to receive the benefits of its services it is consistent with Section 17A of the Act and the rules and regulations thereunder applicable to GSCC.

B. Self-Regulatory Organization's Statement on Burden on Competition

GSCC does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments on the proposed rule change have not yet been solicited or received. GSCC members will be notified of the rule filing and comments will be solicited by a GSCC Important Notice. GSCC will then notify the Commission of any written comments received by GSCC regarding the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of GSCC. All submissions should refer to file number SR–GSCC–94–04 and should be submitted by September 13, 1994.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20567 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

[2] This filing also amends GSCC's rules to expressly provide that if an applicant qualifies for more than one category of netting system membership, GSCC will have the discretion to determine which category of netting system membership that applicant should apply for and which reporting requirements are applicable.

[Release No. 34–34535; File No. SR–NASD–94–40]

Self-Regulatory Organizations; Filing of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Amendments to the Examination Specifications and Study Outline for the Investment Company/Variable Contracts Products Limited Representative (Series 6) Examination

August 16, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 26, 1994, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is proposing amendments to the examination specifications and study outline for the Investment Company/Variable Contracts Products Limited Representative ("Series 6") qualifications examination. The amendments revise materials pertaining to new products, and include new material pertaining to recently effective regulations affecting mutual funds and variable contracts products. The number of questions per examination and the examination time are unaffected by the amendments.

The above-described amendments do not result in any textual changes to the NASD By-Laws, Schedules to the By-Laws, rules, practices or procedures.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The NASD periodically reviews the content of its qualification examinations to determine whether amendments are necessary or appropriate in view of changes pertaining to the subject matter covered by the examinations. The amendments to the Series 6 examination are designed to reflect recent changes in the products offered in industry and to reflect changes in the rules and regulations affecting mutual funds and variable contracts products.

The NASD is requesting that the proposed rule change be effective within 45 days of SEC approval.

The NASD believes that the proposed rule change is consistent with the provisions of Section 15A(g)(3) of the Act in that the proposed changes to the examination are to ensure persons seeking registration in the securities industry have attained the requisite levels of knowledge and competence.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. by order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file numbe SR–NASD–94–40 and should be submitted by September 13, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20565 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34534; File No. SR–NASD–94–42]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Amendments to the Examination Specifications and Study Outline for the Assistant Representative-Order Processing (Series 11) Examination

August 16, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 26, 1994, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is proposing amendments to the examination specifications and study outline for the Assistant Representative-Order Processing ("Series 11") qualifications examination. The amendments revise

[1] 17 CFR 200.30–3(a)(12).

materials pertaining to appropriate job functions, and include new material pertaining to recently effective rules and regulations affecting the securities industry. The number of questions per examination and the examination time are unaffected by the amendments.

The above-described amendments do not result in any textual changes to the NASD By-Laws, Schedules to the By-Laws, Rules, practices or procedures.

II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The NASD periodically reviews the content of its qualification examinations to determine whether amendments are necessary or appropriate in view of changes pertaining to the subject matter covered by the examinations. The amendments to the Series 11 examination are designed to further test appropriate job functions and to reflect changes in the rules and regulations affecting the securities industry.

The NASD is requesting that the proposed rule change be effective within 45 days of SEC approval.

The NASD believes that the proposed rule change is consistent with the provisions of Section 15A(g)(3) of the Act in that the proposed changes to the examination are to ensure persons seeking registration in the securities industry have attained the requisite levels of knowledge and competence.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–94–42 and should be submitted by September 13, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20566 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

[1] 17 CFR 200.30–3(a)(12).

[Rel. No. IC–20485; File No. 812–8996]

GNA Variable Investment Account, et al.

August 16, 1994.

AGENCY: Securities and Exchange Commission ("SEC" or the "Commission").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: GNA Variable Investment Account ("Variable Account"), Great Northern Insured Annuity Corporation ("GNA"), and GNA Distributors, Inc. ("Distributor").

RELEVANT 1940 ACT SECTIONS: Order requested under Section 6(c) for exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order to the extent necessary to permit the deduction from the assets of the Variable Account of a mortality and expense risk charge imposed under certain group allocated variable annuity contracts ("Contracts").

FILING DATE: The application was filed on May 19, 1994 and amended on August 4, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the SEC and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the Commission by 5:30 p.m., on September 12, 1994 and should be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, by certificate. Hearing requests should state the nature of the writers interest, the reason for the request and the issues contested. Persons may request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants: J. Neil McMurdie, Esq., Associate Counsel, Great Northern Insured Annuity Corporation, Two Union Square, Ste. 5600, Seattle, Washington 98111–0490.

FOR FURTHER INFORMATION CONTACT: Joyce M. Pickholz, Senior Counsel, or Michael V. Wible, Special Counsel, at (202) 942–0670, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: Following is a summary of the application. The complete application is available for a

fee from the SEC's Public Reference Branch.

Applicants' Representations

1. GNA is a stock life insurance company organized under the laws of the State of Washington in 1980. It is a wholly owned subsidiary of GNA Corporation, which is a wholly owned subsidiary of General Electric Capital Corporation. GNA is the depositor of the Variable Account. The Variable Account is registered under the Act as a unit investment trust. It was established in 1981, under Washington law, as a separate account of GNA for the purpose of funding certain variable annuity contracts. The assets of the Variable Account will be invested through subaccounts of the Variable Account in shares of corresponding portfolios of investment companies registered under the Act as open-end management investment companies.

2. The Distributor, a wholly owned subsidiary of GNA Corporation, will be the principal underwriter of the Contracts and the certificates issued thereunder ("Certificates"). The Distributor is a broker-dealer registered under the Securities Exchange Act of 1934 and a member of the National Association of Securities Dealers, Inc.

3. The Contract is a group allocated contract pursuant to which specific accounts are maintained for each Participant. The Contract provides for the accumulation of values on a fixed or variable basis and the payment of annuity benefits on a fixed or, in certain cases, a variable basis. The Contract is designed for use in connection with retirement plans which may or may not qualify for special income tax treatment under the Internal Revenue Code of 1986, as amended.

4. Each year GNA will deduct from the value of each Certificate a certificate maintenance charge of $40 as partial compensation for the cost of providing all administrative services attributable to the Contracts and Certificates and the operations of the Variable Account and GNA in connection with the Contracts and Certificates. GNA will waive the charge if at the time of the assessment the Certificate Value is $40,000 or greater. Prior to the commencement of annuity payments ("Annuity Date"), the certificate maintenance charge is deducted on December 31 of each year, except for the first certificate year when a pro-rata portion of the charge will be deducted on December 31. If a full withdrawal of the Certificate's withdrawal value is made on a day other than December 31, the $40 certificate maintenance charge will be deducted from the amount paid. If the Annuity Date is not December 31, a pro-rata portion of the charge is deducted on the Annuity Date.

5. In addition, GNA will deduct from each sub-account each valuation period an administration charge at an annual rate of 0.15% of the average daily value of such sub-account to reimburse GNA for administrative expenses. GNA does not expect to recover from the administration charges any amount in excess of its accumulated administrative expenses. Even though administrative expenses may increase, GNA guarantees that it will not increase the amount of the administration fees as to outstanding Certificates. Applicants will rely on Rule 26a–1 under the Act for the necessary exemptive relief to make such charges.

6. No sales charge will be deducted from purchase payments as they are made. Instead, if a withdrawal is made from a Certificate before the Annuity Date, a withdrawal charge (contingent deferred sales charge) may be assessed against amounts withdrawn attributable to purchase payments that have been in the Certificate less than five complete years. The withdrawal charge is a percentage of the purchase payment being liquidated which percentage declines 5–5–4–3–2% over the first five years since the purchase payment was made. There is no withdrawal charge with respect to earnings accumulated under the Certificate, certain free withdrawal amounts or purchase payments that were made five years or more prior to the withdrawal. In no event may that total withdrawal charges exceed 5% of total purchase payments.

7. Each withdrawal from a Certificate is allocated, first, to the free withdrawal amount, second, to remaining purchase payments which have not been withdrawn previously on a first-in first-out basis, and, third, to any remaining Certificate Value. On the first withdrawal in any certificate year, the Participant may withdraw free of any withdrawal charge an amount equal to 10% of the Certificate Value at the time of the withdrawal. The withdrawal charge is intended to reimburse GNA for compensation paid to cover selling concessions to broker-dealers, preparation of sales literature and other expenses relating to sales activity. Applicants will rely on Rule 6c–8 under the Act for the necessary exemptive relief to permit imposition of the withdrawal charge.

8. GNA assumes a mortality risk and an expense risk under the Contracts and Certificates. The mortality risk is the risk that Annuitants may live for a longer period of time than estimated. GNA assumes this mortality risk by virtue of annuity rates incorporated into the Contract which cannot be changed as to outstanding Certificates. This assures each Annuitant that his longevity will not have an adverse effect on the amount of annuity payments. Also, GNA guarantees that if the Annuitant dies before the Annuity Date, it will pay a death benefit. The expense risk assumed by GNA is the risk that the administration charges or withdrawal charge may be insufficient to cover actual expenses. To compensate it for assuming these risks, GNA will deduct from each sub-account each valuation period a charge at an annual rate of 1.25% of the average daily value of such subaccount, consisting of .75% for the mortality risk and .50% for the expense risk. The rate of the mortality and expense risk charge cannot be increased. If the charge is insufficient to cover the actual cost of the mortality and expense risks undertaken, GNA will bear the loss. Conversely, if the charge proves more than sufficient, the excess will be profit to GNA and will be available for any proper corporate purpose including, among other things, payment of distribution expenses.

Applicants' Legal Analysis

1. Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act require that all payments received under a periodic payment plan certificate be held by a qualified trustee or a custodian and held under arrangements which prohibit any payment to the depositor or principal underwriter except for the payment of a fee, not exceeding such reasonable amount as the Commission may prescribe, for bookkeeping and other administrative services.

2. Applicants represent that the 1.25% mortality and expense risk charge is within the range of industry practice for comparable annuity products. Applicants state that this representation is based upon an analysis of publicly available information about selected similar industry products, taking into consideration such factors as the method used in charging sales loads, any contractual right to increase charges above current levels and the existence of charges against separate account assets for other than mortality and expense risks. GNA will maintain at its principal office, available to the Commission, a memorandum setting forth in detail the products analyzed in the course of, and the methodology and results of, the comparative survey made.

3. Applicants acknowledge that the withdrawal charge will be insufficient to cover all costs relating to the distribution of the Contracts and Certificates and that, if a profit is

realized from the mortality and expense risk charge, all or a portion of such profit may be offset by distribution expenses not reimbursed by the withdrawal charge. Notwithstanding the foregoing, GNA has concluded that there is a reasonable likelihood that the proposed distribution financing arrangements made with respect to the Contracts and Certificates will benefit the Variable Account and the Certificate owners. The basis for such conclusion is set forth in a memorandum which will be maintained by GNA at its principal office and will be available to the Commission. Moreover, GNA represents that the Variable Account will invest only in an underlying mutual fund which undertakes, in the event it should adopt any plan under Rule 12b–1 to finance distribution expenses, to have such plan formulated and approved by a board of directors, a majority of the members of which are not "interested persons" of such fund within the meaning of Section 2(a)(19) of the Act.

Conclusion

Applicants conclude that for the reasons and upon the facts set forth in the application, the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20564 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20477; 812–8610]

IAI Retirement Funds, Inc., et al.

August 16, 1994.

AGENCY: Securities and Exchange Commission ("SEC" or the "Commission").

ACTION: Notice of Application for Exemptions under the Investment Company Act of 1940 (the "1940 Act" or "Act").

APPLICANTS: IAI Retirement Funds, Inc. ("Fund"), Investment Adviser, Inc. ("IAI") and certain life insurance companies and separate accounts.

RELEVANT 1940 ACT SECTIONS: Order request under Section 6(c) for exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the Act and Rules 6e–2(b) (15) and 6e3(T)(b)(15) thereunder.

SUMMARY OF APPLICATION: Applicants seek an order to the extent necessary to permit shares of the Fund and shares of any other investment company that is designed to fund insurance products and for which IAI, or any of its affiliates, may serve as investment adviser, administrator, manager, principal underwriter or sponsor, (the Fund and such other investment companies collectively, "Funds") to be sold to and held by variable annuity and variable life insurance separate accounts of both affiliated and unaffiliated life insurance companies.

FILING DATE: The application was filed on October 8, 1993 and amended on August 12, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on the application by writing to the Secretary of the SEC and serving the Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on September 12, 1994, and should be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate. Hearing requests should state the nature of the request and the issues contested. persons may request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, N.W., Washington, D.C. 20549. Applicants, C/O Christopher J. Smith, 3700 First Bank Place, P.O. Box 357, Minneapolis, Minnesota 55440–0357.

FOR FURTHER INFORMATION CONTACT: Joyce M. Pickholz, Senior Counsel, or Michael V. Wible, Special Counsel, at (202) 942–0670, Division of Investment Management, Office of Insurance Products.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund was organized as a corporation under the laws of the State of Minnesota. It will be comprised of three separately managed series, each of which will have its own investment objective and policies. Additional services may be added to the Fund in the future.

2. IAI serves as the investment adviser and manager of the Fund. IAI is an affiliate of Hill Samuel Group BV ("Hill Samuel"), an international merchant banking and financial services group based in London, England. Hill Samuel, in turn, is owned by TSB Group plc, a publicly-held financial services organization headquartered in London, England.

3. Shares of each series of the Fund may be offered only to insurance company separate accounts to fund variable annuity and variable life insurance contracts ("Contracts"). The Fund initially intends to offer its shares exclusively to variable annuity and flexible premium variable life insurance separate accounts established by Lincoln Benefit Life Company ("Lincoln Benefit") or its affiliates. It is contemplated that, in the future, shares of each series of the Fund would be offered to life insurance company separate accounts offering scheduled or flexible premium variable life insurance or variable annuities, regardless of whether such insurance companies are affiliated.

4. Lincoln Benefit and its affiliates and the other insurance companies to which shares of the Funds will be offered (collectively, "Participating Insurance Companies") will establish their own separate accounts and design their own Contracts. It is anticipated that the Companies will rely on Rule 6e–2 or 6e–3(T) under the Act, although some may rely on individual exemptive orders as well.

5. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts is commonly referred to as "mixed funding". The use of a common investment company as the underlying investment medium for separate accounts of unaffiliated insurance companies is commonly referred to as "shared funding". "Mixed and shared funding" denotes the use of a common management company to fund a variable annuity separate account of one insurance company and the variable annuity or variable life separate accounts of other affiliated and unaffiliated insurance companies. Rule 6e–2(b)(15) precludes mixed and shared funding while Rule 6e–3(T)(b)(15) permits mixed funding but precludes shared funding.

Applicants' Legal Analysis

1. In connection with scheduled premium variable life insurance contracts issued through a separate account registered under the Act as a unit investment trust, Rule 6e2(b)(15) provides partial exemption from sections 9(a), 13(a), 15(a) and 15(b) of the Act. The exemptions granted to a separate account (and any investment adviser, principal underwriter and depositor thereof) by Rule 6e(b)(15), however, are not available with respect to a scheduled premium variable life

insurance separate account that owns shares of an investment company that also offers its shares to a variable annuity separate account of the same or of any affiliated or unaffiliated insurance company ("mixed funding"). In addition, the relief granted by Rule 6e–2(b)(15) is not available if shares of the underlying investment company are offered to variable annuity or variable life insurance separate accounts of unaffiliated insurance companies ("shared funding"). Accordingly, Applicants seek an order exempting scheduled premium variable life insurance separate accounts (and, to the extent necessary, any investment adviser, principal underwriter and depositor of such an account) from Sections 9(a), 13(a), 15(a) and 15(b) of the Act, the Rule 6e–2(b)(15) thereunder, to the extent necessary to permit shares of the Funds to be offered and sold in connection with both mixed funding and shared funding.

2. In connection with flexible premium variable life insurance contracts issued through a separate account registered under the Act as a unit investment trust, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the Act. The exemptions granted to a separate account (and to any investment adviser, principal underwriter and depositor thereof) by Rule 6e–3(T)(b)(15) permit mixed funding of flexible premium variable life insurance but preclude shared funding. Accordingly, Applicants seek an order exempting flexible premium variable life insurance separate accounts (and, to the extent necessary, any investment adviser, principal underwriter and depositor of such an account) from Sections 9(a), 13(a), 15(a) and 15(b) of the Act, and Rule 6e–3(T)(b)(15) (and any comparable permanent rule) thereunder, to the extent necessary to permit shares of the Funds to be offered and sold to separate accounts in connection with shared funding.

3. Section 9(a) of the Act provides that it is unlawful for any company to serve as investment adviser or principal underwriter of any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Section 9(a) (1) or (2). However, Rule 6e–2(b)(15) (i) and (ii) and Rule 6e–3(T)(b)(15) (i) and (ii) provide partial exemption from Section 9(a) under certain circumstances, subject to the limitation discussed above on mixed and shared funding. These exemptions limit the disqualification to affiliated individuals or companies that directly participate in the management or administration of the underlying investment company. The exemptions contained in Rule 6e–2(b)(15) and 6e–3(T)(b)(15) recognize that it is unnecessary to apply Section 9(a) to the thousands of individuals who may be involved in a large insurance company but who would have no connection with the investment company funding the separate account. Applicants believe that it is unnecessary to limit the applicability of the rule merely because shares of the Funds may be sold in connection with mixed and shared funding. Therefore, Applicants assert that applying the restrictions of Section 9(a) serve no regulatory purpose. Indeed, applying such restrictions would increase the monitoring costs incurred by the Participating Insurance Company and, therefore, would reduce the net rates realized by Contract owners.

4. If the limitations on mixed and shared funding are satisfied, Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(iii) provide exemption from the pass-through voting requirements of Sections 13(a), 15(a) and 15(b) of the Act in limited situations. Rule 6e–2(b)(15)(iii)(A) and 6e–3(T)(b)(iii)(A) provide that an insurance company may disregard the voting instructions of its Contract owners with respect to the investments of an underlying investment company or any contract between an investment company and its investment adviser, when an insurance regulatory authority so requires. Rules 6e–2(b)(15)(iii)(B) and 6e–3(T)(b)(15)(iii)(B) provide that the insurance company may disregard Contract owner's voting instructions with regard to changes initiated by the contract holders in the investment company's investment policies, principal underwriter or investment adviser, as follows: voting instructions with respect to a change in investment policies may be disregarded only if such action is reasonable and the insurance company makes a good faith determination that such change would: (1) violate state law; (2) not be consistent with the investment objectives of the separate account; or (3) result in investments that would vary from the general quality and nature of investments and investment techniques used by other separate accounts of the company or of an affiliated life insurance company with similar investment objectives. Voting instructions with respect to a change in a principal underwriter may be disregarded if such action is reasonable. Voting instructions with respect to a change in an investment adviser may be disregarded only if such action is reasonable and the insurance company makes a good faith determination that: (1) the adviser's fee would exceed the maximum rate that may be charged against the separate account's assets; (2) the proposed adviser may be expected to employ investment techniques that vary from the general techniques used by the current adviser; (3) the proposed adviser may be expected to manage the investment company's investments in a manner that would be inconsistent with its investment objectives or in a manner that would result in investments that vary from certain standards.

5. The Applicants submit that Rule 6e–2 recognizes that scheduled premium variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation. Thus, Applicants assert, in adopting Rule 6e–2, the Commission expressly recognized the exemptions from pass-through voting requirements were necessary to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer. Flexible premium variable life insurance contracts are subject to substantially the same state insurance regulatory authority, and therefore, the corresponding provisions of Rule 6e–3(T) presumably were adopted in recognition of the same consideration as the Commission applied in adopting Rule 6e–2. The Applicants argue that these considerations are no less important or necessary when an insurance company funds its separate accounts in connection with shared and mixed funding. Such funding does not compromise the goals of the insurance regulatory authorities or of the Commission. Indeed, Applicants assert, by permitting such arrangements, the Commission eliminates needless duplication of start-up and administrative expenses and potentially increases an investment company's assets, thereby making effective portfolio management strategies easier to implement and promoting other economies of scale.

6. Applicants believe that shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. For example, when different Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require

action that is inconsistent with the requirements of insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. That possibility, however, is no different and no greater than exists when a single insurer and its affiliates offer their insurance products in several states, as currently is permitted.

7. According to the Applicants, affiliations do not reduce the potential, if any exists, for differences in state regulatory requirements. In any event, the conditions set forth below, which are adapted from the conditions included in Rule 6e–3(T)(b)(15), are designed to safeguard against adverse effects that differences among state regulatory requirements may produce. Applicants state that if a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Insurance Products Fund. Similarly, affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company could disregard Contract owner instructions. The potential for disagreement is limited, Applicants assert, by the requirement that disregarding voting instructions be reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard Contract owner voting instructions represents a minority position or would preclude a majority vote approving a particular change, such Participating Insurance Company may be required, at the election of the relevant Insurance Products Fund, to withdraw its separate account's investment in that fund and no charge or penalty will be imposed as a result of such withdrawal. Also, according to Applicants, no one investment strategy can be identified as appropriate to a particular insurance product. Each pool of variable annuity and variable life insurance contract owners is composed of individuals of diverse financial status, age, insurance and investment goals. Those diversities are of greater significance than any differences in insurance products. An investment company supporting even one type of insurance product must accommodate those diverse factors.

8. Applicants contend that there is no reason why the investment policies of a Fund with mixed funding would or should be materially different from what they would or should be if such investment company or series thereof funded only variable annuity or only variable life insurance contracts. Hence, there is no reason to believe that conflicts of interest would result from mixed funding.

9. Applicants state that various factors have kept more insurance companies from offering variable annuity and variable life insurance contracts than currently do so. According to Applicants, these factors include the costs of organizing and operating a funding medium, the lack of expertise with respect to investment management (principally with respect to stock, bond and money market investments) and the lack of public name recognition as investment experts. In particular, some smaller life insurance companies may not find it economically feasible, or within their investment or administrative expertise, to enter the variable contract business on their own. Use of the Insurance Products Funds as common investment media for Contracts would ameliorate these concerns. Participating insurance companies would benefit not only from the investment advisory and administrative expertise of IAI, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Therefore, making the Insurance Products Funds available for mixed and shared funding will encourage more insurance companies to offer Contracts. This should result in increased competition with respect to both Contract design and pricing, which can be expected to result in more product variation and lower charges. Contract owners would benefit because mixed and shared funding should eliminate a significant portion of the costs of establishing and administering separate funds.

Applicants' Conditions

Applicants consent to the following conditions if an order is granted:

1. A majority of the Board of Directors (the "Board") of each Fund will consist of persons who are not "interested persons" thereof, as defined by Section 2(a)(19) of the Act and Rules thereunder and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of the death, disqualification, or bona fide resignation of any director or directors, then the operation of this condition shall be suspended (a) for a period of 45 days if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days if a vote or shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. The Boards will monitor their respective Funds for the existence of any material irreconcilable conflict between the interests of the Contract owners of all separate accounts investing in the Funds. A material irreconcilable conflict may arise for a variety of reasons, including: (a) an action by any state insurance regulatory authority; (b) a change in applicable federal or state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling, no action or interpretative letter, or any similar action by insurance, tax, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Funds are being managed; (e) a difference in voting instructions given by variable annuity Contract owners and variable life insurance Contract owners; or (f) a decision by a Participating Insurance Company to disregard the voting instructions of Contract owners.

3. Participating Insurance Companies and IAI and affiliated advisors will report any such potential or existing conflicts to the Board of any relevant Fund. Participating insurance Companies and IAI and affiliated advisors will be responsible for assisting the appropriate Board in carrying out its responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This includes, but is not limited to, an obligation by a Participating Insurance Company to inform the Board whenever it has determined to disregard Contract owner voting instructions. The responsibility to report such information and conflicts and to assist the Boards will be contractual obligations of all insurers investing in Funds under their agreements governing participation in the Funds, and these responsibilities will be carried out with a view only to the interests of Contract owners.

4. If it is determined by a majority of the Board of a Fund or by a majority of its disinterested directors, that a material irreconcilable conflict exists, the relevant Participating Insurance Companies will, at their expense and to the extent reasonably practicable (as determined by a majority of the disinterested directors), take whatever steps are necessary to remedy or eliminate the irreconcilable material conflict, which steps could include: (a) withdrawing the assets allocable to some or all of the separate accounts from the Fund or any series and reinvesting such assets in a different investment medium, which may include another series of a Fund or another Fund, or submitting the question of

whether such segregation should be implemented to a vote of all affected Contract owners and, as appropriate, segregating the assets of any appropriate group (i.e., variable annuity Contract owners or variable life insurance Contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected Contract owners the option of making such a change; and (b) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of an insurer's decision to disregard Contract owner voting instructions and that decision represents a minority position or would preclude a majority vote, the insurer may be required, at the election of the Fund, to withdraw its separate account's investment in such fund, and no charge or penalty will be imposed as a result of such withdrawal. The responsibility of taking remedial action in the event of a Board determination of an irreconcilable material conflict and bearing the cost of such remedial action will be a contractual obligation of all Participating Insurance Companies under their agreements governing participation in the Funds and these responsibilities will be carried out with a view only to the interests of Contract owners. For purposes of this condition, a majority of the disinterested members of the applicable Board will determine whether or not any proposed action adequately remedies any irreconcilable material conflict, but in no event will the Fund or IAI or affiliated advisors be required to establish a new funding medium for any Contract. No Participating Insurance Company shall be required by this condition to establish a new funding medium for any Contract if an offer to do so has been declined by vote of a majority of Contract owners materially and adversely affected by the irreconcilable material conflict.

5. Any Board's determination of the existence of an irreconcilable material conflict and its implications will be made known promptly and in writing to all Participating Insurance Companies.

6. Participating Insurance Companies will provide pass-through voting privileges to all Contract owners so long as the Commission interprets the Act to require pass-through voting privileges for variable contract owners. Accordingly, the Participating Insurance Companies will vote shares of the Funds held in their separate accounts in a manner consistent with voting instructions timely received from Contract owners. Participating Insurance Companies will be responsible for assuring that each of their separate accounts participating in a Fund calculates voting privileges in a manner consistent with other Participating Insurance Companies. The obligation to calculate voting privileges in a manner consistent with all other separate accounts investing in the Fund will be a contractual obligation of all Participating Insurance Companies under the agreements governing participation in the Fund. The Participating Insurance Companies will vote shares for which they have not received voting instructions as well as shares attributable to them in the same proportion as they vote shares for which they have received instructions.

7. All reports of potential or existing conflicts received by a Board, and all Board action with regard to determining the existence of a conflict, notifying Participating Insurance Companies of a conflict, and determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the appropriate Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

8. Each Fund will notify all Participating Insurance Companies that separate account prospectus disclosure regarding potential risks of mixed and shared funding may be appropriate. Each Fund will disclose in its prospectus that: (a) shares of the Fund are offered in connection with mixed and shared funding; (b) mixed and shared funding may present certain conflicts of interest, and (c) the Board of such fund will monitor for the existence of any material conflicts and determine what action, if any, should be taken.

9. Each Fund will comply with all provisions of the Act requiring voting by shareholders, and, in particular, each Fund will either provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the Act not to require such meetings) or comply with Section 16(c) of the Act, as well as with Section 16(a), and, if applicable, Section 16(b) of the Act. Further, each Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors and with whatever rules the Commission may promulgate with respect thereto.

10. If and to the extent that Rules 6e–2 and 6e–3(T) are amended (or if Rule 6e–3 under the 1940 Act is adopted) to provide exemptive relief from any provision of the act or the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by the Applicants, then the Funds and the Participating Insurance Companies, as appropriate, shall take such steps as may be necessary to comply with Rules 6e–2 and 6e–3(T), as amended, and Rule 6e–3, as adopted, to the extent applicable.

11. No less than annually, the Participating Insurance Companies and/or IAI and affiliated advisors shall submit to each Board such reports, materials, or data as the Board may reasonably request so that the Board may carry out fully the obligations imposed upon it by the conditions contained in the Application. Such reports, materials, and data shall be submitted more frequently if deemed appropriate by the Board. The obligations of the Participating Insurance Companies to provide these reports, materials, and data shall be a contractual obligation of all Participating Insurance Companies under the agreements governing their participation in the Funds.

Conclusion

For the reasons stated above, Applicants believe that the requested exemptions, in accordance with the standards of Section 6(c), are appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and the provisions of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20563 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Release No. 20488; 811–5997]

World Appreciation Fund, Inc.; Notice of Application

August 17, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 ("the Act").

APPLICANT: World Appreciation Fund, Inc.

RELEVANT ACT SECTION: Order requested under section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATES: The application was filed on April 29, 1994, and amended on July 20, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 12, 1994, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicant, 333 South Hope Street, 52nd Floor, Los Angeles, California 90071.

FOR FURTHER INFORMATION CONTACT: H.R. Hallock, Jr., Special Counsel, at (202) 942–0564, or Barry D. Miller, Senior Special Counsel, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant, a Maryland corporation, registered under the Act on January 25, 1990, as an open-end management investment company and filed a registration statement under the Securities Act of 1933. The registration statement was declared effective on July 26, 1990, and applicant commenced an initial public offering of its securities on August 3, 1990. Capital International, Inc. (the "Adviser") is applicant's investment adviser.

2. Applicant was organized in response to the request of a Dutch institutional client of the Adviser. This Dutch institutional client (a related Dutch client also became a shareholder later), another U.S. institutional client of the Adviser (representing a few institutional accounts), and the Adviser were the sole shareholders of applicant from inception. Each of the two institutional client groups had a representative on applicant's board of directors who served as the applicant's two independent directors. In February 1994, the institutional shareholders, through their board representatives, notified the Adviser and the other members of applicant's board that they likely would redeem their shares because of applicant's small size, the lack of interest from additional investors, and inadequate investment results.

3. On April 11, 1994, applicant's board of directors unanimously resolved by written consent to (i) cease operations, (ii) authorize the filing of an application with the SEC under section 8(f) for an order declaring that applicant has ceased to be an investment company, and (iii) authorize the filing of Articles of Dissolution with the Maryland Department of Corporations.

4. Except for the Adviser, all of applicant's shareholders (*i.e.*, the two Dutch investors and the U.S. shareholders group) have redeemed the entire amount of their share interests. The Adviser retained a share interest in order to assure that applicant had sufficient assets to cover unanticipated miscellaneous expenses in connection with the winding-up of applicant's affairs. On April 15, 1994, the Adviser, as the sole remaining shareholder, approved applicant's deregistration, dissolution, and liquidation.

5. As of April 28, 1994, the Adviser owned approximately 3,230 shares owned with an aggregate net asset value of approximately $26,960. At that time, applicant's assets consisted of $21,270 in cash, unamortized prepaid organization expenses of $8,150 (written off in May 1994), and dividends receivable of $8,550 (for which payment had not yet been received and may not be realized). Applicant's liabilities consisted entirely of accrued management fees payable and custody fees payable in the amount of $8,450 and $2,560, respectively. Applicant's assets will not be invested in any securities and any remaining net assets will be paid to the Adviser as the sole shareholder.

6. The only expense incurred by applicant in connection with the liquidation was the accelerated write off of unamortized prepaid organization expense. Because this occurred when the Adviser was the sole shareholder, the expense was paid, in effect, by the Adviser. No other expenses connected with the liquidation have been incurred or are anticipated by applicant.

7. Applicant has no debts or liabilities outstanding. All auditing and legal fees in conjunction with the liquidation have been or will be paid by the Adviser.

8. Applicant is not a party to any litigation or administrative proceedings.

9. Applicant is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–20625 Filed 8–22–94; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF STATE

[Public Notice No. 2051]

Advisory Committee on International Communications and Information Policy Reestablishment

The Department of State is reestablishing the Advisory Committee on International Communications and Information Policy to provide a formal channel for regular consultation and coordination on major economic, social and legal issues and problems in international communications and information policy, especially as these issues and problems involve users of information and communication services, providers of such services, technology research and development, foreign industrial and regulatory policy, the activities of international organizations with regard to communications and information, and developing country interests. The Under Secretary for Management has determined that the committee is necessary and in the public interest.

Members of the committee will be appointed by the U.S. Coordinator for International Communications and Information Policy. The Committee will follow the procedures prescribed by the Federal Advisory Committee Act (FACA). Meetings will be open to the public unless a determination is made in accordance with the FACA Section 10(d), 5 U.S.C. 552b(c) (1) and (4) that a meeting or a portion of the meeting should be closed to the public. Notice of each meeting will be provided in the **Federal Register** at least 15 days prior to the meeting date.

For further information, contact Mr. Timothy C. Finton, Executive Secretary of the committee, at (202) 647–5385.

Dated: August 11, 1994.

Vonya B. McCann,

U.S. Coordinator for International Communications and Information Policy.

[FR Doc. 94–20598 Filed 8–22–94; 8:45 am]

BILLING CODE 4710–45–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Training and Qualifications

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration Aviation Rulemaking Advisory Committee to discuss training and qualifications issues.

DATES: The meeting will be held on September 14, 1994 at noon.

ADDRESSES: The meeting will be held at the National Business Aircraft Association, 1200 18th Street NW Washington, DC, second floor conference room.

FOR FURTHER INFORMATION CONTACT: Ms. Judi Citrenbaum, Office of Rulemaking, (ARM–100) 800 Independence Avenue, SW., Washington, DC 20591. Telephone: (202) 267–9689.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Aviation Rulemaking Advisory Committee (ARAC) to discuss training and qualifications issues. This meeting will be held on September 14, 1994, at noon, at the National Business Aircraft Association in Washington, DC. The agenda for this meeting will include progress reports from the Air Carrier Working Group and the Aircraft Dispatcher Working Group. Each working group Chair will report on the progress of the working group. In addition, the Aircraft Dispatcher Working Group will be presenting a concept briefing on a proposed recommendation to revise part 65, subpart C.

Attendance is open to the interested public but may be limited to the space available. The public must make arrangements in advance to present oral statements at the meeting or may present statements to the committee at any time. In addition, sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on August 17, 1994.

Tom Toula,

Assistant Executive Director for Training and Qualifications, Aviation Rulemaking Advisory Committee.

[FR Doc. 94–20657 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

Flight Service Station at Tucson, AZ; Closure

Notice is hereby given that on July 22, 1994, the Flight Service Station at Tucson, Arizona, closed. Services to the general aviation public of Tucson, formerly provided by this office, are being provided by the Automated Flight Service Station in Prescott, Arizona. This information will be reflected in the next issue of the FAA Organization Statement.

(Sec. 313(a), Stat. 752; 49 U.S.C. 1354).

Issued in Lawndale, California, on July 19, 1994.

Lynore C. Brekke,

Chief of Staff, Western-Pacific Region.

[FR Doc. 94–20660 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–13–M

Federal Highway Administration

Right-of-Way Revolving Fund; Project Selection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: The Federal-Aid Highway Act of 1968 amended section 108 of title 23 U.S.C. by adding section 108(c) establishing the right-of-way revolving fund with an authorization of $300 million from the Highway Trust Fund. Fiscal constraints, in recent years, have limited obligational authority to approximately $43 million per year. However, the demand for revolving funds has greatly exceeded available funds and, as a result, the projects selected for funding have received only approximately $1 for every $3 requested.

The FHWA is publishing this notice to describe the project selection criteria and the process used to ensure that all requests are carefully screened to identify the most deserving projects. Furthermore, the FHWA desires to have the selection process completed in a timely manner so allocations can be made as expeditiously as possible once the funds become available.

FOR FURTHER INFORMATION CONTACT: Mr. Janis Gramatins, Realty Specialist, Special Programs and Evaluation Branch, Office of Right-of-Way, HRW–12, (202) 366–2030; or Mr. Reid Alsop, Office of Chief Counsel, HCC–31, (202) 366–1371, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:30 a.m. to 4 p.m., e.t., Monday through Friday, except legal Federal holidays.

SUPPLEMENTARY INFORMATION: The regulation implementing 23 U.S.C. 108(c) is found at 23 CFR Part 712, Subpart G, Right-of-Way Revolving Fund. Additional guidance is found at 23 CFR Part 130, Subpart D, Advance Right-of-Way Revolving Funds.

Since the inception of the program the revolving fund has generated a high level of activity. Thirty-nine States including Puerto Rico have taken advantage of the fund with total allocations to date of $714 million. Currently there are 19 States actively involved with allocations of $244 million. Over the past several years, average annual requests for revolving funds have been $180 million. The demand and competition for these funds makes it incumbent upon us to ensure that the most deserving projects are selected. Further, these funds must be allocated as expeditiously as possible once they become available.

The Process

No later than the first day of August of each year, the FHWA solicits from each State a request for projects, asking for their response by the first week of September. A State's request, which may include more than one project, is evaluated and ranked, by the FHWA Division office. The Division office forwards the State's request with the Division's evaluation and ranking to the Regional office which, in turn, evaluates and ranks all requests before forwarding them to FHWA Headquarters', Office of Right-of-Way.

Criteria

The following criteria are used at each level of evaluation.

Cost Savings

The primary intent of the program is to advance funds sufficiently early in project development to avoid escalating real estate costs or relocation costs associated with developed properties. An analysis of the estimated cost savings is required.

Type of Facility

High-type, usually controlled access roadways serving important national or regional (sub-State) transportation needs with significant planned ADT, and

passenger transit facilities, will receive priority consideration.

Environmental Assessment

The potential of the project to enhance the environment or minimize negative environmental impacts of development is important. Because highway funds generally cannot be expended on a project until the appropriate environmental document has been prepared and approved, the status of the document is an important ranking factor. If the appropriate document has not been approved the expected date of approval should be so stated in the application.

Use of Prior Allocations

With demand for revolving funds outstripping supply by a 3 to 1 margin, the past performance, if any, of a State in returning the funds so they can be "revolved" to other projects is an important criterion.

Obligational Ability

All funds must be obligated in the same year in which the funds are allocated. Any factors that may hinder the obligation of funds during the fiscal year in which they are allocated, must be addressed. Other criteria to be considered include total project cost, corridor preservation innovation, project connectivity [i.e., the relationship of the project with other highway, or intermodal, projects], and the national geographical distribution of funds available for allocation.

Project Selection and Notification

The FHWA uses a multi-disciplinary team to evaluate and recommend projects for funding. If a recommendation is approved a preliminary allocation of funds for the selected project is made to the specific State through the FHWA field offices. Authority to obligate all or part of the allocated funds is granted when a State actually proceeds with land acquisition.

Authority: 23 U.S.C. 101(a), 108, and 315; 49 CFR 1.48 (b); 23 CFR 1.32.

Issued on: August 16, 1994.

Rodney E. Slater,

Federal Highway Administration.

[FR Doc. 94–20675 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–22–P

[FHWA Docket 94–18]

General Material Requirements; Buy America Requirements

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed nationwide waiver of Buy America for pig iron and processed, pelletized, and reduced iron ore; request for comments.

SUMMARY: The FHWA requests public comment on a proposed nationwide waiver of the Buy America requirements for certain iron components used in the manufacture of steel and/or iron materials. Based on the findings of a nationwide review, the FHWA has reason to believe that the supply from domestic sources of pig iron and processed, pelletized, and reduced iron ore is not adequate to permit full compliance with the Buy America requirements. The proposed waiver would specifically address this shortage by permitting the use of pig iron and processed, pelletized, and reduced iron ore manufactured outside of the United States to be used in the domestic manufacturing process for steel and/or iron materials used in Federal-aid highway construction projects.

DATES: Written comments must be received on or before October 24, 1994.

ADDRESSES: Submit signed, written comments to FHWA Docket 94–18, Federal Highway Administration, Room 4232, HCC–10; 400 Seventh Street, SW.; Washington, D.C. 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. David R. Geiger, Office of Engineering (202) 366–0355 or Mr. Wilbert Baccus, Office of the Chief Counsel (202) 366–0780, Federal Highway Administration, 400 Seventh Street SW., Washington, D.C. 20590.

SUPPLEMENTARY INFORMATION: In accordance with 23 CFR 635.410(c)(6), the FHWA hereby provides notice that it is considering a nationwide waiver of the requirements of 23 CFR 635.410. Buy America requirements, for the manufacture of pig iron and processed, pelletized, and reduced iron ore. Section 635.410 provides, with exceptions, that no Federal-aid highway construction project using steel or iron materials is to be authorized to proceed unless all manufacturing processes, including the application of coatings for such materials, occur in the United States.

Pig iron is made from molten iron which has been cast in the shape of "pigs" as it comes from a blast furnace. Pig iron is thus considered a manufactured product, and the making of pig iron is an initial step in the manufacturing process of steel and iron materials. Processing, pelletizing, and reducing iron ore are methods by which raw iron ore is improved to produce enriched ore. Processed, pelletized, and reduced iron ore are alternatives to pig iron, and are also considered to be manufactured products used to manufacture steel and iron materials.

A recent nationwide review supports a conclusion that the usage of foreign pig iron and processed, pelletized, and reduced iron ore is necessary because an adequate domestic source is not available. Therefore, the FHWA proposes to waive application of the Buy America requirements to pig iron and processed, pelletized, and reduced iron ore. Materials not specifically included in the waiver would remain subject to the Buy America requirements.

The basis for this proposed nationwide waiver is that pig iron and processed, pelletized, and reduced iron ore are not produced in the United States in sufficient and reasonably available quantities which are of a satisfactory quality. Therefore, imposing Buy America requirements on these materials is not in the public interest.

The FHWA is requesting comments on this proposed nationwide waiver and the availability of a domestic supply of the materials included in the proposed waiver. The FHWA's Buy America requirements contained in 23 CFR 635.410 are based on section 165 of the Surface Transportation Assistance Act of 1982 (Pub. L. 97–424, 96 Stat. 2136), as amended by Pub. L. 98–229, § 10, 98 Stat. 55, 57, and Pub. L. 102–240, §§ 1041(a) and 1048, 105 Stat. 1914, 1993, 1999.

(23 U.S.C. 315; 49 CFR 1.48; 23 CFR 635.410)

Issued on: August 16, 1994.

Rodney E. Slater,

Federal Highway Administrator.

[FR Doc. 94–20676 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–22–P

Maritime Administration

Change of Name of Approved Trustee

Notice is hereby given that effective January 1, 1993, Security Pacific National Trust Company (New York), with offices at 2 Rector Street, 9th Floor, New York, New York 10006, has changed its name to BankAmerica National Trust Company.

Dated: August 15, 1994.

By Order of the Maritime Administrator.

James E. Saari,

Acting Secretary.

[FR Doc. 94–20570 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–81–M

Merger of Approved Trustee

Notice is hereby given that The Connecticut National Bank and Trust Company, N.A., Hartford, Connecticut, merged with and into the State Street Bank and Trust Company, 750 Main Street, Boston, Massachusetts, under the name of State Street Bank and Trust Company as the surviving corporation in the merger.

Dated: August 15, 1994.

By Order of the Maritime Administrator.

James E. Saari,

Acting Secretary.

[FR Doc. 94–20572 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–81–M

Merger of Approved Trustee

Notice is hereby given that Irving Trust Company, New York, New York, merged with and into The Bank of New York, 101 Barclay Street, New York, New York 10286, under the name of The Bank of New York as the surviving corporation in the merger.

Dated: August 15, 1994.

By Order of the Maritime Administrator.

James E. Saari,

Acting Secretary.

[FR Doc. 94–20571 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–81–M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 94–70]

Petitioner's Desire to Contest Decision Denying Domestic Interested Party Petition Concerning Classification of Flat Goods with Outer Surface of Plastic Sheeting, of Reinforced or Laminated Plastics

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of petitioner's desire to contest decision on domestic interested party petition.

SUMMARY: This document advises the public of the desire of two interested parties to contest Customs decision denying their petition requesting reclassification of flat goods with outer surface of plastic sheeting, of reinforced or laminated plastics. The petitioners have advised Customs of their intention to file an action in the U.S. Court of International Trade.

DATES: August 23, 1994.

FOR FURTHER INFORMATION CONTACT: Carlos Halasz, Commercial Rulings Division, U.S. Customs Service, (202) 482–7050.

SUPPLEMENTARY INFORMATION:

Background

On December 30, 1993, Customs published a notice in the **Federal Register** (58 FR 69301) inviting public comments concerning a domestic interested party petition, filed pursuant to section 516, Tariff Act of 1930, as amended (19 U.S.C. 1516). The petitioners are Amity Leather Company, a domestic manufacturer of flat goods, and the Luggage and Leather Goods Manufacturers of America, Inc. (LLGMA), a trade association for domestic producers of luggage, leather goods and plastic flat goods. The petition relates to the tariff classification of flat goods, with outer surface of plastic sheeting, of reinforced or laminated plastics.

Schedule 7, Part 12, Subpart A, Headnote 2, of the prior tariff, the Tariff Schedules of the United States (TSUS), provided that the term "reinforced or laminated plastics" was limited to articles composed of rigid plastic materials. Item 706.42, TSUS, provided for flat goods of reinforced or laminated plastics, dutiable at 5.5 cents/pound + 4.6 percent *ad valorem*. Accordingly, this item was limited to flat goods composed of rigid plastics. Flat goods with an outer surface of non-rigid plastics were classified in item 706.61, TSUS. The applicable rate of duty was 20 percent *ad valorem*.

Subheading 4202.32.1000, Harmonized Tariff Schedule of the United States (HTSUS), provides for articles of a kind normally carried in the pocket or in the handbag, with outer surface of sheeting of plastic, of reinforced or laminated plastics. The applicable rate of duty is 12.1 cents/kilogram + 4.6 percent *ad valorem*. Following the enactment of the HTSUS, Customs initially concluded that the definition of "reinforced or laminated plastics" contained in the TSUS continued to be applicable under the HTSUS. *See* Headquarters Ruling Letters (HRL) 083261, dated September 14, 1989; HRL 084020, dated June 7, 1989; HRL 083415, dated May 18, 1989. In these decisions, Customs recognized that the term was not defined in the HTSUS. However, Customs determined that the definition of this phrase as set forth in the TSUS represented its common and commercial meaning. Hence, flat goods with an outer surface of non-rigid plastics were precluded from subheading 4202.32.1000, HTSUS. Pursuant to subheading 4202.32.2000, HTSUS, the applicable rate of duty for these articles was 20 percent *ad valorem*.

This issue was revisited in HRL 950048, dated March 2, 1992. In that decision, Customs observed that the classification of a container under heading 4202, HTSUS, is made with reference to its outer surface. Subheading 4202.32, HTSUS, provides for articles of a kind normally carried in the pocket or handbag (a classification encompassing articles similar to "flat goods" under the TSUS), with outer surface of plastic sheeting. The breakout for "reinforced and laminated plastics" occurs at the eight-digit national classification level beneath the six-digit international breakout for plastic sheeting. Consequently, the breakout for "reinforced or laminated plastics" must be interpreted in a manner consistent with the fact that its superior six-digit subheading provides for "plastic sheeting."

Heading 3921, HTSUS, when read in conjunction with heading 3920, HTSUS, provides for sheets of cellular plastic which have been reinforced, laminated or similarly combined with other materials. The Explanatory Note to heading 3921 states in pertinent part that the heading covers cellular sheets of plastics not elsewhere described which have been "reinforced, laminated, supported or similarly combined with other materials." The terms "reinforced" and "laminated" in this context refer to methods by which cellular plastic sheeting may be "combined" with other materials (e.g., textiles). Thus, cellular plastic sheeting that is "reinforced" means that the sheeting has been strengthened or supported by means of a supplementary backing. Cellular plastic sheeting that has been "laminated" means that the sheeting has been united or bonded with other materials. In HRL 950983, dated June 15, 1992, Customs determined that the classification of flat goods with outer surface of noncellular plastic should also be made with reference to Chapter 39, HTSUS.

As the terms "laminated" and "reinforced" are discussed in these terms with regard to plastic sheeting, Customs found that it was erroneous to interpret the phrase "reinforced or laminated plastics" to be limited to rigid plastics. Such an interpretation would allow the terms "reinforced" and "laminated" to have one meaning at the eight-digit classification level, and

another at the six-digit classification for plastic sheeting. As the superior heading in this instance is that for plastic sheeting, Customs concluded that the terms should be interpreted consistently so as to refer to methods of combining plastic sheeting with other materials.

Petitioner's Viewpoint

Petitioners observe that the phrase "reinforced or laminated plastics" is not defined in the HTSUS and contend that there is no support within the HTSUS for Customs interpretation of these terms. Specifically, petitioners state that in HRL 950048, Customs adopted a definition of "laminated" that is unsupported by the text of the HTSUS. Moreover, petitioners refer to subheadings 6506.10.30 (safety head gear), 9401.80.20 (seats), 9403.70.40 (furniture), 9403.90.40 (other furniture and parts thereof), HTSUS, where the phrase "reinforced or laminated" appears. The petitioners allege that the classification of goods under these provisions has been limited to rigid plastics.

Alternatively, petitioners argue that the terms "reinforced" and "laminated" as utilized in connection with plastic sheeting of heading 3921, have no bearing on the interpretation of the phrase "reinforced or laminated plastics." Hence, plastic sheeting of heading 3921, HTSUS, that has been reinforced or laminated with other materials, describes goods distinct from goods composed of "reinforced or laminated plastics."

Furthermore, petitioners note that heading 3921, which encompasses plastic sheeting combined with other materials, is not limited to plastic sheeting which has been reinforced or laminated. The petitioners infer from HRL 950048 that Customs is of the opinion that all materials classified within heading 3921 constitute reinforced and laminated plastics of subheading 4202.32.1000. From this premise, petitioners conclude that Customs has erroneously narrowed the scope of heading 3921.

The arguments set forth above have been advanced to demonstrate that the meaning of the phrase "of reinforced or laminated plastics" in subheading 4202.32.1000 cannot be found within the HTSUS or its accompanying Explanatory Notes. As a result, petitioners contend that the meaning of the phrase must be in accordance with congressional intent and its common and commercial meaning.

Documents have been submitted to support the proposition that the common and commercial meaning of the phrase "reinforced or laminated plastics" limits its scope to rigid plastics and that the HTSUS was enacted with the intent to continue this interpretation. For example, petitioners allude to the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100–418, which states that the conversion from the TSUS to the HTSUS was intended to be essentially revenue neutral. Our attention is directed to the fact that subheading 4202.32.1000, HTSUS, which provides for the articles at issue, with outer surface of plastic sheeting, of reinforced or laminated plastics, is dutiable at the same rate previously applicable for flat goods, of reinforced or laminated plastics, under item 706.42, TSUS. Moreover, petitioners have proffered excerpts from plastic industry publications and other sources which limit "reinforced or laminated plastics" to rigid plastics.

Based on the foregoing, petitioners conclude that Customs must reconsider HRL 950048 and its progeny and classify the instant merchandise within subheading 4202.32.2000, HTSUS.

Comments

Four comments were received in opposition to the petition. As a threshold issue, the commenters argue that the LLGMA is not an "interested party" as set forth in Section 516(a), Tariff Act of 1930, as amended (19 U.S.C. 1516(a)). Consequently, the LLGMA lacks standing to bring the domestic interested party petition.

The commenters observe that the statutory definition for the phrase "reinforced or laminated plastics" contained in the TSUS was not carried over to the HTSUS. This omission is interpreted as evidence that Congress intended not to apply the TSUS definition to the HTSUS. Accordingly, Customs should not limit the provision for "reinforced or laminated plastics" to rigid plastics.

The commenters also reason that the common and commercial meaning of the term "reinforced or laminated plastics" is its plain meaning. Citing lexicographic sources, they contend that the plain meaning of the terms "reinforce" and "laminate" is consistent with Customs interpretation. Furthermore, the commentators assert that the definition petitioners advance is a narrow and technical interpretation which is not commonly utilized in the flat goods industry.

Finally, the commenters note that under the HTSUS flat goods are classified according to their outer surface. On the other hand, under the TSUS flat goods were classified under the doctrine of chief value. Hence, the provisions in the TSUS and HTSUS encompassing what are commercially known as flat goods are not analogous. For this reason, the commenters conclude that arguments concerning the goal of revenue neutrality are misplaced.

Response to Comments

Standing of petitioner: Section 516(a), Tariff Act of 1930, as amended (19 U.S.C. 1516(a)) states that a domestic "interested party" may petition for a classification determination. An "interested party" includes "a trade or business association a majority of whose members are manufacturers, producers, or wholesalers in the United States of goods of the same class or kind as the designated imported merchandise." The petitioners observe that the LLGMA is a trade association with a membership which includes a substantial number of flat goods producers. However, a majority of its members are luggage and briefcase producers. Noting that the membership of the LLGMA does not include a majority of flat goods producers, the commenters reason that the LLGMA lacks standing to bring the petition.

Heading 4202, HTSUS, provides for flat goods such as spectacle cases, purses and wallets, as well as briefcases, suitcases and traveling bags. These articles are linked by the common physical characteristic that they are generally designed to carry, store or protect personal effects. We are of the opinion that manufacturers of briefcases and luggage operate in the same trade as producers of flat goods. On this basis, Customs concludes that flat good, briefcase and luggage manufacturers are engaged in the production of goods of the same class or kind for the purposes of section 1516(a)(2)(C). Accordingly, the LLGMA has standing to bring this petition.

Tariff Classification: The instant merchandise are flat goods with an outer surface of plastic sheeting combined with textile fabric. At the six-digit classification level, these goods are classified according to their outer surface of plastic sheeting. As noted above, HRL 950048 identified heading 3921, HTSUS, as legal support for its findings. The Explanatory Note to heading 3921 indicates that the terms "reinforced" and "laminated" are examples of how plastic sheeting may be "combined" with other materials. We are of the opinion that it would be anomalous to interpret the words "reinforced" and "laminated" in a different fashion at the six and eight digit classification levels. Therefore,

Customs concludes that there is adequate legal support from within the HTSUS to support its position.

Customs interprets the provision for "reinforced or laminated plastics" within heading 4202, HTSUS, in light of the fact that it appears beneath a subheading for plastic sheeting. In this context, the terms "reinforced" and "laminated" are not limited to rigid plastics. The petitioners have directed our attention to other subheadings within the HTSUS which may limit "reinforced or laminated plastics" to rigid plastics. Assuming for the sake of argument only that this is the case, these provisions do not occur beneath superior headings or subheadings providing for plastic sheeting. For this reason, they do not bear on the interpretation of subheading 4202.32.1000, HTSUS.

Finally, Customs recognizes that heading 3921, HTSUS, describes plastic sheeting which has been combined in any manner with other materials. Thus, the heading includes, but is not limited to, plastic sheeting which has been reinforced or laminated. In HRL 950048, Customs did not conclude, as petitioners suggest, that all goods of heading 3921, HTSUS, are to be regarded as reinforced or laminated plastics. Customs merely referred to heading 3921, HTSUS, for the proposition that the meaning of the terms "reinforced" and "laminated" refer to manners in which plastic sheeting may be combined with other materials. Hence, HRL 950048 has no effect on the scope of heading 3921, HTSUS.

Decision on Petition and Notice of Petitioner's Desire to Contest

After careful analysis of the petition, supplemental submissions, and all comments received, Customs has decided to continue its current practice of classifying flat goods with outer surface of plastic sheeting, of reinforced or laminated plastics. As the structure of the HTSUS and its accompanying Explanatory Notes form the basis of this decision, Customs does not reach the issues of congressional intent or the common and commercial meaning of the phrase "of reinforced or laminated plastics." The petitioners were informed by letter dated April 4, 1994 [CLA–2 CO:R:C:T 953936 ch], through their counsel, that Customs is of the opinion that the current classification is correct and their petition is therefore denied.

In response to Customs decision to deny the petition, on April 29, 1994, the petitioners filed notice of their intention to contest the decision in accordance with section 516(c), Tariff Act of 1930, as amended (19 U.S.C. 1516(c)), and section 175.23 Customs Regulations (19 CFR 175.23).

Customs has reconsidered the matter in light of the petitioners' letter, but remains of the opinion that its April 4, 1994, decision is correct. That decision will stand in the absence of a contrary judgment rendered by the U.S. Court of International Trade or the U.S. Court of Appeals for the Federal Circuit.

Authority

This notice is published under the authority of section 516(c), Tariff Act of 1930, as amended (19 U.S.C. 1516(c)), and section 175.24, Customs Regulations (19 CFR 175.24).

Drafting Information

The principal author of this document was Carlos H. Halasz, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Approved: August 10, 1994.

George J. Weise,

Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 94–20689 Filed 8–22–94; 8:45 am]

BILLING CODE 4820–02–P

Office of Thrift Supervision

Bay Federal Savings Bank, West Palm Beach, FL; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in Subdivision (C) of Section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator Bay Federal Savings Bank, West Palm Beach, Florida ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 15, 1994.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20613 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

Coral Coast Federal Savings Bank, Boynton Beach, FL; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in Subdivision (C) of Section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator Coral Coast Federal Savings Bank, Boynton Beach, Florida ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 15, 1994.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20615 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

Guardian Federal Savings Association, Huntington Beach, CA; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in Subdivision (C) of Section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator Guardian Federal Savings Association, Huntington Beach, California ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 29, 1994.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20612 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

The Guardian Bank, a Federal Savings Bank, Boca Raton, FL; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in Subdivision (C) of section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator to The Guardian Bank, a Federal Savings Bank, Boca Raton, Florida ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 15, 1994.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20614 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

Hansen Federal Savings Bank, Palm Beach Gardens, FL; Notice of Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in Subdivision (C) of section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator to Hansen Federal Savings Bank, Palm Beach Gardens, Florida ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 22, 1994.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20611 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–55; OTS No. 02332]

Bridgeville Savings Bank, F.S.B., Bridgeville, PA; Approval of Conversion Application

Notice is hereby given that on August 12, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Bridgeville Savings Bank, F.S.B., Bridgeville, Pennsylvania, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, and the Northeast Regional Office, Office of Thrift Supervision, 10 Exchange Plaza Center, 17th Floor, Jersey City, New Jersey 07302.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20610 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–54; OTS No. 05273]

Carver Federal Savings Bank, New York, NY; Approval of Conversion Application

Notice is hereby given that on August 12, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Carver Federal Savings Bank, New York, New York, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, and the Northeast Regional Office, Office of Thrift Supervision, 10 Exchange Plaza Center, 17th Floor, Jersey City, New Jersey 07302.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20609 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–50; OTS No. 00144]

First Federal Savings Bank of Lynchburg, Lynchburg, VA; Approval of Conversion Application

Notice is hereby given that on July 14, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Federal Savings Bank of Lynchburg, Lynchburg, Virginia, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Southeast Regional Office, Office of Thrift Supervision, 1465 Peachtree Street, NE, Altanta, Georgia 30309.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20605 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–45; OTS No. 11990]

Flushing Savings Bank, FSB, Flushing, NY; Approval of Conversion Application

Notice is hereby given that on July 15, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Flushing Savings Bank, FSB, Flushing, New York, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Northeast Regional Office, Office of Thrift Supervision, 10 Exchange Plaza Centre, 17th floor, Jersey City, New Jersey 07302.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20600 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–47; OTS No. 05245]

Guthrie Federal Savings and Loan Association, Guthrie, OK; Approval of Conversion Application

Notice is hereby given that on July 22, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Guthrie Federal Savings and Loan Association, Guthrie, Oklahoma, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, and the Northeast Regional Office, Office of Thrift Supervision, 122 W. John Carpenter Freeway, Suite 600, Irving, Texas 75039.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20602 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–52; OTS No. 04650]

Inter-Boro Savings and Loan Association, Cherry Hill, NJ; Approval of Conversion Application

Notice is hereby given that on August 8, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Inter-Boro Savings and Loan Association, Cherry Hill, New Jersey, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Northeast Regional Office, Office of Thrift Supervision, 10 Exchange Plaza, 18th Floor, Jersey City, New Jersey 07302.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20607 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–51; OTS No. 03666]

Life Savings and Loan Association, Norfolk, VA; Approval of Conversion Application

Notice is hereby given that on August 9, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Life Savings and Loan Association, Norfolk, Virginia, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, and the Southeast Regional Office, Office of Thrift Supervision, 1475 Peachtree Street, NE, Atlanta, Georgia 30309.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20606 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–48; OTS No. 03569]

Milton Federal Savings and Loan Association, West Milton, OH; Approval of Conversion Application

Notice is hereby given that on July 22, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Milton Federal Savings and Loan Association, West Miltion, Ohio, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, Suite 800, Chicago, Illinois 60601–4360.

Dated: August 17, 1994.

By the Office of Thrift Supervision

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20603 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–46; OTS No. 01583]

Russell Federal Savings and Loan Association, Russell, KY; Approval of Conversion Application

Notice is hereby given that on July 14, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Russell Federal Savings and Loan Association, Russell, Kentucky, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, Suite 800, Chicago, Illinois 60601–4360.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

[FR Doc. 94–20601 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–49; OTS No. 00296]

Southwest Virginia Savings Bank, FSB, Roanoke, VA; Approval of Conversion Application

Notice is hereby given that on July 29, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Southwest Virginia Savings Bank, FSB, Roanoke, Virginia, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Southeast Regional Office, Office of Thrift Supervision, 1475 Peachtree Street, NE, Atlanta, Georgia 30309.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

Kimberly M. White,

Corporate Technician.

[FR Doc. 94–20604 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

[AC–53; OTS No. 00707]

Sulphur Springs Loan and Building Association, Sulphur Springs, TX; Approval of Conversion Application

Notice is hereby given that on August 12, 1994, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Sulphur Springs Loan and Building Association, Sulphur Springs, Texas, convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Midwest Regional Office, Office of Thrift Supervision, 122 W. John Carpenter Freeway, Suite 600, Irving, Texas 75039.

By the Office of Thrift Supervision.

Dated: August 17, 1994.

[FR Doc. 94–20608 Filed 8–22–94; 8:45 am]

BILLING CODE 6720–01–M

UNITED STATES INFORMATION AGENCY

Reporting and Information Collection Requirements Under OMB Review

AGENCY: United States Information Agency.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed or established reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the Agency has made such a submission. The information collection activity involved with this program is conducted pursuant to the mandate given to the United States Information Agency in accordance with P.L. 98–111 as amended by P.L. 101–246. USIA is requesting clearance approval for an information collection entitled "USIA Responsible Officer Training Survey." This is a new information collection. The information sought is primarily used for developing training for responsible officers of exchange visitors programs. Estimated burden hours per response is fifteen (15) minutes. Respondents will be required to respond only one time.

DATES: Comments are due on or before September 2, 1994.

COPIES: Copies of the Request for Clearance (SF–83), supporting statement, transmittal letter and other documents submitted to OMB for approval may be obtained from the USIA Clearance Officer. Comments on the items listed should be submitted to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USIA, and also to the USIA Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Agency Clearance Officer, Ms. Debbie Knox, United States Information

Agency, M/ADD, 301 Fourth Street SW., Washington, DC 20547, telephone (202) 619–5503; and OMB review: Mr. Jefferson Hill, Office of Information And Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, telephone (202) 395–7340.

SUPPLEMENTARY INFORMATION: Public reporting burden for this collection of information (Paper Work Reduction Project: OMB No. to be assigned) is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the United States Information Agency, M/ADD, 301 Fourth Street SW., Washington, DC 20547; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Title: USIA Responsible Officer Training Survey.

Form Number: IAP–136.

Abstract: Data from this information collection will be used by USIA's Office of the General Counsel (GC) to help develop training sessions for responsible officers.

Proposed Frequency of Responses:
No. of Respondents—200
Recordkeeping Hours—.15
Total Annual Burden—50

August 17, 1994.

Rose Royal,

Federal Register Liaison.

[FR Doc. 94–20585 Filed 8–22–94; 8:45 am]

BILLING CODE 8230–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Resolution of Complaint of Price-Undercutting of Subsidized Cheese Imports

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of Resolution of Complaint of Price-Undercutting of Subsidized Cheese Imports.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice that the European Commission and the Government of Austria have provided the necessary assurances that the duty-paid wholesale price of imported Swiss or Emmentaler cheese produced in Austria, Denmark and Germany will not be less than the domestic wholesale market price of similar articles produced in the United States.

FOR FURTHER INFORMATION CONTACT: Elizabeth Haines, Senior Economist, Office of Agricultural Affairs (202) 395–3077, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: On June 27, 1994, the United States Trade Representative received a letter from the Acting Secretary of Agriculture informing him of the Acting Secretary's finding that imported subsidized quota Swiss or Emmentaler cheese produced in Austria, Denmark and Germany is undercutting the wholesale price of Swiss cheese produced and sold in the United States. During the investigation period of December 1993 through April 1994, the average duty-paid wholesale price was $1.55 per pound, $1.56 per pound, and $1.12 per pound of blocks of Swiss or Emmentaler cheese imported from Austria, Denmark, and Germany, respectively, compared to the average domestic wholesale market price of $1.76 per pound of blocks of Swiss cheese produced in the United States. During the same period, the average duty-paid wholesale price was $1.80 per pound and $1.69 per pound for cuts, slices, loaves, etc., imported from Denmark and Germany, respectively, compared to the average domestic wholesale market price of $1.85 per pound for cuts, slices, loaves, etc., of Swiss cheese produced in the United States. Also during the period of investigation, the average duty-paid wholesale price was $1.37 per pound for trims and end pieces imported from Austria compared to $1.54 from trims and end pieces produced in the United States.

On June 29, in accordance with section 702(c)(2) of the Trade Agreements Act of 1979 (the Act) (19 U.S.C. 1202 note), the Office of the United States Trade Representative notified the European Commission and the Government of Austria of the price-undercutting determination made by the Acting Secretary of Agriculture, requested that corrective action be taken, and asked for appropriate assurances concerning the commitments made in the Arrangement Between the United States and Austria Concerning Cheeses, and the Arrangement Between the United States and the European Union Concerning Cheeses.

On July 11, the Government of Austria notified the United States Trade Representative that measures have been taken to ensure that the duty-paid wholesale price of imported Swiss or Emmentaler cheese produced in Austria will not be less than the domestic wholesale market price of similar cheese produced in the United States. On July 14, the European Commission notified the United States Trade Representative that measures have been taken to ensure that the duty-paid wholesale price of imported Swiss or Emmentaler cheese produced in the European Union will not be less than the domestic wholesale market price of similar cheese produced in the United States.

In addition, the European Commission and the Government of Austria gave assurances that they will respect the price commitments in the Arrangement. Since the above notifications by the European Commission and the Government of Austria have occurred within the 15-day period provided in section 702(c)(3) of the Act, no further action is required pursuant to section 702.

Michael Kantor,

United States Trade Representative.

[FR Doc. 94–20650 Filed 8–22–94; 8:45 am]

BILLING CODE 3190–01–M

Sunshine Act Meetings

Federal Register
Vol. 59, No. 162
Tuesday, August 23, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of August 22, 29, September 5, and 12, 1994.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of August 22

Monday, August 22

9:00 a.m.
Discussion of Interagency Issues (Closed—Ex. 9)

9:00 a.m.
Briefing on Investigative Matters (Closed—Ex. 5 and 7)

2:00 p.m.
Briefing on Additional Changes to Part 100 Rulemaking and Proposed Update on Source Term (Public Meeting)
(Contact: Leonard Soffer, 301–415–6574)

Tuesday, August 23

9:30 a.m.
Periodic Briefing on EEO Program (Public Meeting)
(Contact: Vandy Miller, 301–415–7380)

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting)
a. Gulf States Utilities Company—Appeal of LBP–94–3 (River Bend Station Unit 1) (Tentative)
(Contact: Cecilia Carson, 301–504–1625)
b. Sequoyah Fuels Corporation's and General Atomics' Appeals of the Atomic Safety and Licensing Board's Orders, LBP–94–5 and LBP–94–8 (Docket No. 40–8027–EA) (Tentative)
(Contact: Cecilia Carson, 301–504–1625)
c. Sequoyah Fuels Corporation's Appeal of the Atomic Safety and Licensing Board's Order LBP–94–19 (Docket No. 40–8027–EA) (Tentative)
(Contact: Cecilia Carson, 301–504–1625)
d. Sequoyah Fuels Corp. General Atomics' Petition for Review and/or Motion for Directed Certification (Docket No. 40–8037–EA) (Tentative)
(Contact: Roland Frye, 301–504–3505)

Week of August 29—Tentative

Tuesday, August 30

2:30 p.m.
Briefing on PRA Policy Statement and Action Plan (Public Meeting)
Contact: Thomas Hiltz, 301–504–1105)

Wednesday, August 31

10:00 a.m.
Briefing by U.S. Enrichment Corporation (Public Meeting)

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of September 5—Tentative

Wednesday, September 7

2:00 p.m.
Briefing on Information Technology Strategic Plan (Public Meeting)
(Contact: Richard Hartfield, 301–415–5818)

Thursday, September 8

1:30 p.m.
Periodic Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting)
(Contact: John Larkins, 301–415–7360)

3:00 p.m.
Briefing on NRC High Level Radioactive Waste Performance Assessment Program (Public Meeting)
(Contact: Norman Eisenberg, 301–415–7285)

4:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Friday, September 9

9:30 a.m.
Briefing on HLW Issues by NWTRB, State of Nevada, Local Governments and Native Americans (Public Meeting)
(Contact: Chip Cameron, 301–504–1642)

1:30 p.m.
Protocol for Study of Thyroid Disease in Belarus as a Result of the Chernobyl Accident (Public Meeting)
(Contact: Shlomo Yaniv, 301–415–6239)

4Week of September 12—Tentative

There are no meetings scheduled for the Week of September 12.

ADDITIONAL INFORMATION: By a vote of 3–0 on August 19, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Discussion of Interagency Issues" (Closed—Ex. 9) be held on August 22, and on less than one week's notice to the public.

By a vote of 3–0 on August 19, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Briefing on Investigative Matters" (Closed—Ex. 5 and 7) be held on August 22, and on less than one week's notice to the public.

By a vote of 3–0 on August 19, the Commission determined pursuant to U.S.C. 552(e) and § 9.107(a) of the Commission's rules that "Affirmation of Sequoyah Fuels Corp. General Atomics' Petition for Review and/or Motion for Directed Certification (Docket No. 40–8027–EA)" (Public Meeting) be held on August 22, and on less than one week's notice to the public.

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 504–1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill, (301) 504–1661.

Dated: August 19, 1994.

William M. Hill, Jr.

SECY Tracking Officer, Office of the Secretary.

FR Doc. 94–20840 Filed 8–19–94; 3:09 pm]

BILLING CODE 7590–01–M

federal register

Tuesday
August 23, 1994

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310, et al.
Final Monograph for OTC Nasal Decongestant Drug Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 341, and 369

[Docket No. 76N–052N]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Nasal Decongestant Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion caused by acute or chronic rhinitis) are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on nasal decongestant drug products that have come to the agency's attention. Also, this final rule amends the regulation that lists nonmonograph active ingredients by adding those OTC nasal decongestant ingredients that have been found to be not generally recognized as safe and effective and that were not previously listed in the regulation. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 23, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (Cough-Cold Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by December 8, 1976. Reply comments in response to comments filed in the initial comment period could be submitted by January 7, 1977.

In accordance with § 330.10(a)(10), the data and information considered by the Cough-Cold Panel were put on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulations, in the form of tentative final monographs, for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products were issued in the following segments: Anticholinergics and expectorants, bronchodilators, antitussives, nasal decongestants, antihistamines, and combinations. The fourth segment, the tentative final monograph for OTC nasal decongestant drug products, was published in the **Federal Register** of January 15, 1985 (50 FR 2220). Interested persons were invited to file by May 15, 1985, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by May 15, 1985. New data could have been submitted until January 15, 1986, and comments on the new data until March 17, 1986.

In the **Federal Register** of June 19, 1992 (57 FR 27658), FDA published a notice of proposed rulemaking to amend the tentative final monograph for OTC nasal decongestant drug products to modify the drug interaction precaution statement as follows:

Drug interaction precaution. Do not take this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression or psychiatric or emotional conditions), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

In the **Federal Register** of July 30, 1992 (57 FR 33663), FDA published a correction to change the wording of the first sentence of the statement from, "Do not take * * *" to "Do not use * * *." In the **Federal Register** of August 6, 1992 (57 FR 34734), the agency extended the comment period to October 5, 1992, to obtain additional comments on whether the drug interaction precaution statement should be expanded to include MAO B drugs, such as selegiline. The agency asked whether the proposed drug interaction precaution statement should be expanded to read:

Drug interaction precaution. Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

The agency invited comments and information on interactions between selegiline and sympathomimetic amines and asked whether, from a public health perspective, it would be appropriate to expand the drug interaction precaution statement, as indicated. Final agency action occurs with the publication of this final monograph, which is the final rule establishing a monograph for OTC nasal decongestant drug products (see comment 22 in section I.E. of this document.)

The Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel) reviewed safety and effectiveness data on two oral nasal decongestant ingredients, phenylephrine hydrochloride and phenylpropanolamine hydrochloride (in lozenge form), and classified these nasal decongestants in Category III in its report on OTC oral health care drug products published in the **Federal Register** of May 25, 1982 (47 FR 22920). In the tentative final monograph for OTC oral health care anesthetic/analgesic, astringent, debriding agent/oral wound cleanser, and demulcent drug products published in the **Federal Register** of January 27, 1988 (53 FR 2448), the agency referred the data on these two oral nasal decongestant ingredients to the rulemaking for OTC nasal decongestant drug products because most of the nasal decongestant ingredients had been reviewed earlier and more extensively by the Cough-Cold Panel. In this final rule, phenylephrine hydrochloride for use as an oral nasal decongestant, which would include use in a lozenge dosage form, is a monograph ingredient. However, because of still unresolved safety issues concerning phenylpropanolamine preparations, the agency is deferring action on this drug. (See the **Federal Register** of January 15, 1985, 50 FR 2220 at 2221.) Therefore, phenylpropanolamine preparations will not be categorized or further discussed in this document.

Propylhexedrine was formerly a scheduled drug both domestically and internationally, but had an exclusion under 21 CFR 1308.22 that allowed it to

be sold OTC in the United States in inhaler products. In September 1990, the 27th World Health Organization (WHO) Expert Committee on Drug Dependence examined the international scheduling of propylhexedrine. Based on new data, the Expert Committee recommended to WHO that propylhexedrine be removed from international control. On June 10, 1991, the United States was notified that propylhexedrine had been decontrolled internationally, thus obviating the need for domestic control. The Drug Enforcement Administration issued a final rule in the **Federal Register** of December 3, 1991 (56 FR 61372) to remove propylhexedrine from the schedules of the Controlled Substances Act.

The ingredient l-desoxyephedrine is currently a scheduled drug in the United States. However, a specific marketed inhaler product containing this topical nasal decongestant ingredient has an exclusion that allows it to be sold OTC in the United States (see 21 CFR 1308.22). Thus, this ingredient for topical use in an inhaler dosage form could be included in this final monograph (See paragraph 19 in section II of this document.)

The agency's final rule, in the form of a final monograph, for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products is also being published in segments. Final agency action on all OTC nasal decongestant drug products, except those containing phenylpropanolamine, occurs with the publication of this final monograph, which establishes §§ 341.3(f) and (g), 341.20, and 341.80 for OTC nasal decongestant drug products in part 341 (21 CFR part 341). Combination drug products containing nasal decongestant ingredients are addressed in the tentative final monograph on OTC combination cough-cold drug products, which was published in the **Federal Register** of August 12, 1988 (53 FR 30522). A final rule for those combination products will be published in a future issue of the **Federal Register**.

The OTC drug procedural regulations (21 CFR 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Category II or III, the term "nonmonograph conditions" is used.

As discussed in the proposed rule on OTC nasal decongestant drug products (50 FR 2220), the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after August 23, 1995, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application (hereinafter called application). Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC nasal decongestant drug products, 11 drug manufacturers, 1 drug manufacturers' association, 1 health care professional, and 11 consumers submitted comments. Copies of the comments received are on public display in the Dockets Management Branch (address above). Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

In proceeding with this final monograph, the agency has considered all comments and objections, and the changes in the procedural regulations.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of August 9, 1972 (37 FR 16029) or to additional information that has come to the agency's attention since publication of the notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Conclusions on the Comments

A. General Comments on OTC Nasal Decongestant Drug Products

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 to 9472); in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260); and in paragraph 2 of the preamble to the tentative final monograph for OTC cough-cold combination drug products, published in the **Federal Register** of August 12, 1988 (53 FR 30522 at 30524). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. Two comments stated that nasal decongestants cause dependency and should not be available OTC. One of the comments, from a physician, observed that a relatively large number of individuals with upper respiratory symptoms (often associated with allergic rhinitis) begin taking nasal decongestants and find that the symptoms persist for longer than 1 week and often persist for several months at a time. Furthermore, if the individuals attempt to use nasal decongestants for the duration of this period, there is a high likelihood that they will develop a tolerance of the nasal mucosa to the decongestant effect of the medication. When the individuals try to stop the medication, they develop a significant obstructive congestion of the nasal mucosa from which they only apparently find relief through continued use of the medicine. Also, the medication appears to lose its effect, somewhat, with continued use over a long period of time, thus requiring even more frequent use. The comment stated this was particularly a problem with

nasal sprays and cited several patients who persisted in using OTC nasal sprays every 2 hours or so despite intensive efforts by the physician to discourage such use. The comment contended that easy accessibility of these products, due to their OTC status, makes it almost impossible to wean some patients from the use of nasal decongestants. The second comment, from a consumer, opposed OTC use of nasal decongestants because of experience in which a member of the family became dependent on nasal decongestant sprays in order to breathe.

The agency has reexamined the Cough-Cold Panel's discussion regarding "rebound congestion." The Cough-Cold Panel stated the following:

> Because of the remarkable degree of nasal decongestion which follows topical application of these agents, there is the tendency on the part of patients to administer nasal decongestants too frequently and for too long a period of time. Continued and intense drug-induced vasoconstriction can lead to rebound dilation of the blood vessels as the drug effect subsides. This phenomenon, which intensifies nasal congestion and perpetuates the rhinitis condition, has been termed "rebound congestion." This problem is minimized if topically applied decongestants are administered in accordance with label directions at recommended intervals for periods not exceeding 3 days. (See 41 FR 38312 at 38396.)

Although aware that continued use of nasal decongestant drugs might result in rebound congestion, the Cough-Cold Panel thought that the clinical and marketing data it reviewed showed these drugs to be safe and effective when used according to label directions. Therefore, the Cough-Cold Panel concluded that such drugs should be available for OTC use and it recommended the following warning: "Do not use this product for more than 3 days. If symptoms persist, consult a physician" (41 FR 38312 at 38423).

In the tentative final monograph, the agency concurred with the Cough-Cold Panel's recommendations that all nasal drops, sprays, and jellies, and propylhexedrine in inhalant form be labeled to limit use to not more than 3 days so as to discourage prolonged use and that a doctor should be consulted if symptoms persisted after 3 days of use. (See § 341.80 (c)(2)(iii)(*a*) and (c)(2)(vi) in 50 FR 2220 at 2239.) The ingredient l-desoxyephedrine in inhalant form had to bear the same warning except it stated 7 days instead of 3 days. (See § 341.80(c)(2)(ii) and discussion in 50 FR 2220 at 2225.)

In addition, the agency has reviewed comments to the Cough-Cold Panel's report concerning rebound congestion and finds seven comments from allergists who specifically mentioned oxymetazoline, xylometazoline, naphazoline, or phenylephrine as causing rebound congestion due to prolonged or excessive use (Ref. 1). Moreover, the agency has reviewed adverse drug reaction reports for the years 1976 to 1993 and finds that the two most frequently reported adverse effects of marketed OTC topical nasal decongestant drug products are rebound congestion and drug dependence (Ref. 2).

The agency believes that the OTC availability of topical nasal decongestants is beneficial to many consumers who seek temporary relief from nasal congestion and concurs with the Cough-Cold Panel's recommendations that these products can be safely used according to label directions. The agency is concerned, however, in view of comments submitted to this rulemaking and adverse drug reactions reported to FDA, that consumers may not be adequately alerted and warned of the problem of rebound congestion, which may be caused by prolonged or excessive use of these preparations. Thus, the agency believes that the 3-day use warning should be expanded to explain to consumers the reason for the 3-day limitation for use of topical nasal decongestants.

Therefore, in this final monograph the warning in § 341.80(c)(2)(iii)(A) for adults, in § 341.80(c)(2)(viii) for children under 12 years of age, and in § 341.80 (c)(2)(v) and (c)(2)(ix) for propylhexedrine in inhalant form for adults and children, respectively, is expanded as follows: "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

The agency concludes that these additions to the labeling included in this final monograph will provide for the safe and effective use of OTC topical nasal decongestant drugs.

References

(1) Comments No. C0026, C0077, C0092, C0095, C0118, C0120, C0130, Docket No. 76N–0052, Dockets Management Branch.

(2) Department of Health and Human Services, Food and Drug Administration, "Spontaneous Reporting System, Line Listing of Adverse Reports: Nasal–76–93," 1976–1993, in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

3 Referring to the statements in the tentative final monograph for OTC antihistamine drug products, "* * * antihistamines did not reduce nasal obstruction and therefore did not aid in sinus drainage. To the contrary, the studies indicated that antihistamines may sometimes further aggravate nasal obstruction" (50 FR 2200 at 2203), one comment expressed concern that FDA not use this statement as a basis for disagreeing with the Cough-Cold Panel's Category I classification of combinations containing an antihistamine and an oral nasal decongestant.

In the tentative final monograph for OTC antihistamine drug products (50 FR 2200 at 2203), the agency made the statements quoted above as part of its discussion that antihistamines are ineffective for the treatment of sinus congestion. It was not the agency's intent to use the statements as a basis for disagreeing with combination drug products containing an antihistamine and an oral nasal decongestant.

In the tentative final monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, the agency agreed with the Cough-Cold Panel's Category I classification of combinations containing an antihistamine and an oral nasal decongestant (53 FR 30522 at 30539). In view of the data reviewed by the Cough-Cold Panel that support combinations containing an antihistamine and an oral nasal decongestant (41 FR 38312 at 38326) and the extensive data on such combinations that are available to the agency, the agency reiterates the Cough-Cold Panel's recommendation that combinations containing an antihistamine and an oral nasal decongestant are safe, effective, and rational.

B. Comments on Switching Prescription Nasal Decongestant Active Ingredients to OTC Status

4. Several comments opposed the availability of oxymetazoline hydrochloride and xylometazoline hydrochloride as OTC topical nasal decongestants. The comments also opposed the availability of pseudoephedrine hydrochloride and pseudoephedrine sulfate at dosage levels twice as high as previously permitted for OTC use. The comments expressed concern that these drugs could be dangerous or harmful to many people, young and old alike. One comment felt that self-medicating with nasal decongestants might cause damage to "mucous-lined passages" and that consumers might not know if they have one of the conditions (i.e., heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland) listed in the warnings for these

products. Two comments approved of FDA's requirement for warning information in labeling and supported the OTC availability of these drugs. Another comment mentioned, however, that many persons unfortunately do not or cannot read labels.

As discussed in the tentative final monograph, the agency reviewed safety and effectiveness data on oxymetazoline hydrochloride, xylometazoline hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate and agreed with the Cough-Cold Panel that these active ingredients could be generally recognized as safe and effective for OTC use when appropriately labeled. (See 50 FR 2220 at 2222 to 2223, 2229 to 2230, and 2233 to 2234.) The comments did not submit any data to show that these ingredients should not be available OTC.

To enhance the safe use of these ingredients, in the tentative final monograph, the agency modified several of the Cough-Cold Panel's recommendations regarding pseudoephedrine hydrochloride and pseudoephedrine sulfate as oral nasal decongestants, and oxymetazoline hydrochloride and xylometazoline hydrochloride as topical nasal decongestants. For example, the agency reduced the maximum adult oral dosage of pseudoephedrine preparations from 360 milligrams (mg) to 240 mg in 24 hours (50 FR 2229 to 2230). The agency also proposed that topical nasal decongestant products containing oxymetazoline hydrochloride and xylometazoline hydrochloride not be used in children under 6 years of age unless recommended by a doctor (50 FR 2222 to 2223).

Regarding one comment's concern that self-medicating with OTC nasal decongestants might cause damage to "mucous-lined passages," the comment did not explain its use of the term "mucous-lined passages," nor did it submit any data to substantiate its claim that OTC nasal decongestants at the recommended dosages can cause damage to "mucous-lined passages." Although frequent and prolonged use of topical nasal decongestants may lead to rebound congestion (see comment 2 in section I.A. of this document), the agency is unaware of possible long-term damage to "mucous-lined passages" if a topical nasal decongestant drug product is used for a short period of time and according to directions. As the Cough-Cold Panel pointed out, the problem of rebound congestion is not a factor with use of the orally administered nasal decongestants (41 FR 38312 at 38397).

Regarding the comment's concern that consumers might not know if they have one of the conditions listed in the warnings for these products (i.e., heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland), the agency notes that there are additional warnings in the monograph informing consumers that topical nasal decongestants should not to be used for more than 3 days and that oral nasal decongestants should not be used for more than 7 days, and if symptoms persist, to consult a doctor. Because these products are intended to be used for a limited time only, the agency believes that the risk of adverse effects at the recommended oral or topical dosages is minimal. Moreover, the agency believes that persons having most of the conditions listed in the warning (heart disease, thyroid disease, diabetes, difficulty in urination) would be aware of their condition (because of other apparent symptoms) and be under medical treatment, and the warning instructs them not to use the product unless directed by a doctor.

There is a concern, however, for individuals having certain conditions that may have no apparent symptoms. High blood pressure is a well-known example of such a disease. Persons with high blood pressure may be unaware that they have the condition and may use a nasal decongestant without being aware that the nasal decongestant drug can affect the condition. Nasal decongestants and other sympathomimetic drugs can produce a variety of adverse effects and should be used with caution in individuals with high blood pressure (Refs. 1 and 2). Of the estimated 58 million hypertensive individuals in the United States, about 20 percent (approximately 11 million) do not know they have high blood pressure (Ref. 3). If high blood pressure is not treated, problems such as heart failure, stroke, and kidney disease may occur. The agency believes that periodic medical examinations, high blood pressure screening programs, and education are the most important tools to detect undiagnosed hypertensive individuals. The agency encourages consumers to take advantage of such programs to help minimize the risks associated with undiagnosed high blood pressure.

Regarding the comment that many persons unfortunately do not or cannot read labels, the agency notes that section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)) requires that a drug be labeled "* * * in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The labeling in this final monograph is intended to meet this statutory requirement.

The safety and effectiveness data on oxymetazoline hydrochloride, xylometazoline hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate that were reviewed by the Cough-Cold Panel and the agency support the agency's conclusion that these ingredients can be generally recognized as safe and effective for OTC use when marketed in accordance with the labeling and other conditions established in this final monograph.

References

(1) Berkow, R., editor, "The Merck Manual," 16th ed., Merck and Co., Rahway, NJ, p. 192, 1992.

(2) "Drug Evaluations Annual," American Medical Association, Milwaukee, WI, pp. 407–408, 1991.

(3) Berkow, R., editor, "The Merck Manual," 16th ed., Merck and Co., Rahway, NJ, p. 419, 1992.

C. Comments on Specific OTC Nasal Decongestant Active Ingredients

5. One comment requested that the agency place camphor (0.1 percent), eucalyptus oil (0.025 percent), and menthol (0.05 percent) in Category I as individual OTC topical/inhalant nasal decongestants for use in a hot steam vaporizer; and place the ingredients camphor (4.73 to 5.3 percent), eucalyptus oil (1.2 to 1.3 percent), and menthol (2.6 to 2.8 percent) in Category I as individual OTC topical/inhalant nasal decongestants for use in a chest rub ointment form. The comment submitted three controlled clinical studies (CRD 83–10, CRD 82–10, and CRD 82–09) and two pilot clinical studies (CRD 74–63A and CRD 75–39) of the individual ingredients to support its request (Ref. 1). The first study (CRD 83–10) concerned the single aromatics in steam from a vaporizer. The other four studies concerned the single aromatics in petrolatum applied to the chest and throat. In response to the agency's concerns regarding the statistical analysis of study CRD 83–10 (Ref. 2), the comment provided a statistical reanalysis of the study (Ref. 3).

The agency has reviewed the data and determined that the clinical studies do not support the reclassification of the individual ingredients as requested by the comment. Although one study (CRD 83–10) shows some statistically significant evidence of the effectiveness of camphor, eucalyptus oil, and menthol as topical/inhalant nasal decongestants administered by steam vaporization, there are certain statistical problems

with the data that make the results questionable. Although the statistical reanalysis provides some statistical evidence of efficacy, the agency concludes that stronger evidence of efficacy from a second study is needed (Ref. 4). The other four studies (CRD 82–10, CRD 82–09, CRD 74–63A, and CRD 75–39) are insufficient to demonstrate the effectiveness of camphor, eucalyptus oil, and menthol as individual topical/inhalant nasal decongestants in a chest rub ointment form.

Study CRD 83–10 was designed to determine the individual topical/inhalant nasal decongestant effect of camphor, eucalyptus oil, and menthol vaporized in steam compared to unmedicated steam. In this single-blind, parallel study, 234 subjects with acute upper respiratory tract infection were equally divided into 4 treatment groups (vaporized camphor, eucalyptus oil, menthol, or steam control). Nasal airway resistance was measured with a rhinomanometer before treatment, every 15 minutes (min) for the first hour and every 30 min for the second hour. The investigator reported that when the individual observation time points were examined, the results indicated that each ingredient was significantly more effective in reducing nasal congestion than steam alone at each 15-min interval over the first hour (all $p \leq 0.02$) and over the entire 2-hour exposure period.

Although the comment claimed that study CRD 83–10 showed each active ingredient to be statistically better than placebo (steam) control, the agency has determined that the data and the reanalysis of study CRD 83–10 alone do not provide adequate support for the monograph status of camphor, eucalyptus oil, and menthol as individual topical/inhalant nasal decongestant ingredients for several reasons. First, there was an improper use of baseline values; for example, the baseline values were measured 15 min and 0 min before treatment, but only the 0-minute measurement was used as the baseline value. Conversely, in study CRD 82–10, the baseline values were taken as the average of 15- and 0-min pretreatment measurements. Second, the use of the Bartlett's test to verify the assumption of homogeneity of the variances in the logarithm-transformed data demonstrated that the homogeneity of the variances was found to be acceptable for only the first 60 min, i.e., variances among treatment groups were not significantly different for the periods of 15, 30, 45, and 60 min. However, statistically significant differences were found at 90 min, 120 min, and overall, with the steam control group showing an unacceptable consistently higher variance than the active ingredient treatment groups. Third, the reanalysis of the logarithm-transformed rhinomanometer measurement data by the Kruskal-Wallis test (a nonparametric test) showed that the active ingredients were statistically better than the steam control group only within the first hour of the study and not significantly better than the steam control group after one hour. These weak findings would be further weakened if adjustment for p-value for multiple testing of time points were made.

Should another study be done, a repeated measurement analysis (i.e., an overall analysis) of the rhinomanometer data needs to consider the increase in variance over all time points to remedy the problem of repeated testings. Further, if variances in results increase over the time period in an additional study, the reason for this occurrence needs to be addressed.

Study CRD 82–10 compared the nasal decongestant effects of the individual ingredients camphor 5.2 percent, eucalyptus oil 1.3 percent, and menthol 2.8 percent in petrolatum against a petrolatum placebo in 40 subjects per group with acute coryzal rhinitis (common cold) using a randomized parallel design. The investigator reported that there were no statistically significant differences between treatments with respect to objectively measured nasal congestion for the total study population. Study CRD 82–09 used the same protocol as CRD 82–10, with 39 to 42 subjects per group. This study also did not show any statistically significant differences between test and control treatments. In conclusion, both studies, CRD 82–10 and CRD 82–09, provide no statistically significant data that the individual active ingredients were better than petrolatum control in reducing nasal congestion in subjects with acute coryzal rhinitis.

Regarding the two pilot studies (CRD 74–63A and CRD 75–39), the agency notes that both studies used the same protocol. The studies were randomized crossover studies using subjects with colds. Comparisons were made by objective measurement of nasal airway resistance using anterior rhinomanometry. Study CRD 74–63A compared a commercial product containing a combination of volatile aromatic oils with the following individual ingredients: Eucalyptus oil 1.33 percent in a petrolatum base, turpentine oil 5.12 percent in a petrolatum base, and petrolatum (placebo). Study CRD 75–39 compared the nasal decongestant effects of a commercial product containing a combination of volatile aromatic oils with the following individual ingredients: Camphor 4.7 percent in a petrolatum base, menthol 2.6 percent in a petrolatum base, and petrolatum (placebo). A summary statistical analysis of studies CRD 74–63A and CRD 75–39, prepared by the comment's statistician (Ref. 2), states that these studies show no statistical advantages for the components over petrolatum and that the absence of statistical significance in these studies is not unexpected because of the small sample sizes of the treatment groups. Furthermore, significant residual effects were detected in the data from these studies, indicating that the crossover model was inappropriate. The agency concludes that studies CRD 74–63A and CRD 75–39 do not provide adequate data to demonstrate the effectiveness of camphor, eucalyptus oil, and menthol as individual topical/inhalant active ingredients when administered in a chest rub ointment form.

In conclusion, the submitted data are insufficient to generally recognize camphor, eucalyptus oil, and menthol as safe and effective as individual topical/inhalant nasal decongestant active ingredients, either in petrolatum applied to the chest and throat or in a hot steam vaporizer. Therefore, at this time, these ingredients for these uses are not being included in the final monograph for OTC nasal decongestant drug products. Combination products containing these ingredients are discussed in the tentative final monograph for OTC cough-cold combination drug products, published in the **Federal Register** of August 12, 1988 (53 FR 30522). In that tentative final monograph nasal decongestant use was discussed in comment 59 (53 FR 30522 at 30550), and antitussive use was discussed in comments 56 and 57 (53 FR 30522 at 30547 to 30548). These combination products will be addressed in the final monograph for OTC cough-cold combination drug products, which will be published in a future issue of the **Federal Register.**

The agency's detailed comments and evaluations of the data are on file in the Dockets Management Branch (Ref. 3).

References

(1) "VapoRub," Vol. 1, Richardson-Vicks, Inc., submitted as part of Comment No. C0212, Docket No. 76N–052N, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to E. J. Hanus, Richardson-Vicks, Inc., coded as LET095, Docket No. 76N–052N, Dockets Management Branch.

(3) Letter from E. J. Hanus, Richardson-Vicks, Inc., to W. E. Gilbertson, FDA, coded as LET096, Docket No. 76N–052N, Dockets Management Branch.
(4) Letter from W. E. Gilbertson, FDA, to E. J. Hanus, Richardson-Vicks, Inc., coded as LET109, Docket No. 76N–052N, Dockets Management Branch.

6. One comment submitted data (Refs. 1 and 2) to support the effectiveness of ephedrine and its salts as an oral nasal decongestant. The data consisted of four studies (CRD 78–04, CRD 78–06, CRD 78–26, and CRD 78–27) (Refs. 3 through 6) in which the data were pooled and analyzed as one study; three single-investigator studies (CRD 74–9, CRD 74–57, and CRD 76–61) (Refs. 7, 8, and 9); and four articles from the scientific literature (Refs. 10 through 13). Additional statistical information (Ref. 2) was provided by the comment in response to the agency's request (Ref. 14). The comment also noted that the agency concluded in the tentative final monograph for OTC bronchodilator drug products (47 FR 47520 at 47527, October 26, 1982) that ephedrine and its salts at a 25-mg oral dose as a bronchodilator are safe for OTC use. The comment requested that ephedrine and its salts be placed in Category I for oral nasal decongestant use at a dosage of 8 to 25 mg every 4 hours, not to exceed 75 mg in 24 hours.

The pooled study (studies CRD 78–04, CRD 78–06, CRD 78–26, and CRD 78–27) (Refs. 3 through 6) involved a total of 445 subjects obtained by 4 different investigators. These were parallel studies with 60 subjects participating in CRD 78–04, 54 subjects in CRD 78–06, 202 subjects in CRD 78–26, and 129 subjects in CRD 78–27. Each study group was subdivided into three subgroups. The subjects in each subgroup received a single dose of aqueous solution containing ephedrine sulfate 8 mg/dose, ephedrine sulfate 12 mg/dose, or an aqueous placebo. Nasal airway resistance was measured by Vick's Rhinomanometer at 30, 60, 90, 120, and 180 min after the dose was given.

In analyzing the data in the pooled study, the agency noted that out of the four studies, there were only sporadic statistically significant rhinomanometer data differences in favor of ephedrine 12 mg over placebo in Study CRD 78–26 (Ref. 5). For subjective subject ratings of nasal congestion, there were only sporadic statistically significant differences in favor of ephedrine 12 mg over placebo in Study CRD 78–26. With sample sizes ranging from 17 to 45 subjects per treatment group, there should be adequate statistical power to detect a significant clinical difference if it exists. However, both rhinomanometer measurements and subject ratings of nasal congestion data failed to clearly differentiate ephedrine from placebo in these studies.

In the pooled data analysis, significant treatment by center interaction was found in 3 of the 5 time-point analyses ($p \leq 0.15$). Six of 25 time-point analyses (24 percent) showed that placebo was the same or better than ephedrine. A statistical reanalysis of the data (Ref. 2) did not establish any statistical evidence, either in the pooled data or in any of the individual studies, that ephedrine is superior to the placebo control in reducing nasal congestion. The agency also notes that this reanalysis of the data using the Kruskal-Wallis test (a nonparametric version of "one-way" analysis of variance) does not remove the issue of center interaction. Further, the mathematical model that was used to analyze the rhinomanometer data provides an extremely low R-square value. Hence, the agency considers these findings as casting doubt on the poolability of these efficacy data and believes that conclusions should be drawn based on the results from individual studies. Therefore, the agency concludes that the data in the pooled study fail to provide substantive statistical evidence of effectiveness.

The single-investigator studies (CRD 74–9, CRD 74–57, and CRD 76–61) (Refs. 7, 8, and 9) involved a total of 316 subjects. Study CRD 74–57 (Ref. 8) did not show any statistically significant difference between ephedrine and placebo. This parallel-design, double-blind, computer-randomized study used nasal airway flow rate measurements to compare the nasal decongestant effect of solutions of ephedrine sulfate 8 mg/30 milliliters (mL), ephedrine sulfate 16 mg/30 mL, phenylpropanolamine hydrochloride 37.5 mg/30 mL, and a 30 mL placebo vehicle solution containing no active ingredient. Two doses were given, 4 hours apart. A total of 189 subjects with nasal congestion due to coryza was divided among the 4 treatment groups. The results showed that the phenylpropanolamine solution had the greatest effect on increasing nasal airflow when compared with both doses of ephedrine and the placebo. Both doses of ephedrine produced significantly greater flow than placebo overall, but not at any of the individual time intervals. The effect of ephedrine 16 mg/30 mL also approached significance at the final evaluation (2 hours after the second dose). There were no significant differences noted in the subjective evaluation of runny nose, post-nasal drip, watery eyes, and number of sneezes. However, the use of the ephedrine 16 mg/30 mL solution seemed to be beneficial in reducing the number of "nose blows."

Study CRD 74–9 (Ref. 7) also did not demonstrate any statistically significant difference between ephedrine and placebo. This was a parallel-design study employing 86 subjects with nasal congestion due to coryza. The subjects were divided into 3 subgroups with 29 subjects receiving ephedrine sulfate 8 mg/30 mL (aqueous vehicle), 29 subjects receiving phenylpropanolamine hydrochloride 25 mg/30 mL (aqueous vehicle), and 28 subjects receiving 30 mL of the aqueous vehicle alone. It was noted in this study that sorbitol was added to the test solution given to the first 34 subjects. However, when 3 subjects (1 in each of the 3 treatment groups) experienced intestinal distress, the remaining 52 subjects were given an aqueous test solution without the sorbitol. The agency notes that, in general, no clinical conclusions can be derived from this study because of the differing results obtained between the sorbitol and nonsorbitol-containing test solutions.

Only one study, CRD 76–61 (Ref. 9), showed some favorable results. This study was a double-blind, computer-randomized crossover study involving 41 subjects having nasal congestion due to coryza. Eighteen subjects received 8 mg of ephedrine sulfate and 23 subjects received 12 mg of ephedrine sulfate on one of two test days, both administered in 30 mL of aqueous vehicle. All 41 subjects received aqueous vehicle placebo on the other test day. Nasal airway resistance was used as an objective measure of nasal congestion and changes therein. Resistance was measured by Vick's Rhinomanometer before treatments were administered and at 30, 60, 90, 120, and 180 min after treatments, which were 24 hours apart. Subjective ratings were also recorded before each measurement. Subjectively, subjects using the 8-mg and 12-mg doses of ephedrine sulfate perceived an improvement in nasal decongestion to a statistically significant extent, but the comparisons with placebo results were not significant. As determined by nasal airway resistance measurements, both the 8-mg and 12-mg doses of ephedrine sulfate decreased the nasal congestion of subjects to a statistically significant extent overall, in comparison with the results obtained with the placebo. However, the agency considers the results of the study to be inconsistent because the ephedrine 8-mg group obtained some favorable results over placebo at 60 min after treatment, but the ephedrine 12-mg group obtained

only sporadically favorable results. In addition, the 12-mg group obtained significant results only within the first hour after treatment, while the 8-mg group did not obtain significant results until 1 hour after treatment. These discrepancies are not adequately explained. The agency believes that the findings in both the pooled studies (Refs. 3 through 6) and the individual study CRD 76–61 (Ref. 9) would be further weakened if adjustments for multiple testings of hypotheses were made.

With regard to the four articles (Refs. 10 through 13) from the literature, the agency finds that these articles are not supportive of either the pooled study or the individual studies. The McLaurin, Shipman, and Rosedale study (Ref. 10) was reviewed by the Cough-Cold Panel, which found that it did not contain any conclusive data to support claims of nasal decongestant effectiveness for 8 to 12 mg ephedrine doses contained in OTC drug products (41 FR 38312 at 38408). Although the Cough-Cold Panel stated that the study demonstrated nasal decongestant effectiveness of orally administered ephedrine sulfate in doses of 25 mg, the agency considers the study inadequate to establish effectiveness because it was not controlled. The study by Gowen and Nedzel (Ref. 11) and the study by Mothersill (Ref. 12) are not adequate because the results were subjective and ephedrine was not studied alone, but in combination with other active ingredients. Likewise, the Aschan study (Ref. 13) also was not a single active ingredient study.

Although safety is not a problem, as the comment noted, based on the lack of adequate data to demonstrate effectiveness, ephedrine and its salts are not being included as oral nasal decongestant ingredients in this final monograph. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 15).

References

(1) Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(2) Comment No. SUP003, Docket No. 76N–052N, Dockets Management Branch.
(3) Hayes, S.L., "Multicenter-Pooled Study," draft of unpublished study (CRD 78–04), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(4) Fulco, O.J., "Multicenter-Pooled Study," draft of unpublished study (CRD 78–06), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(5) doPico, G.A., "Multicenter-Pooled Study", draft of unpublished study (CRD 78–26), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(6) Diamond, P.H., "Multicenter-Pooled Study," draft of unpublished study (CRD 78–27), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(7) Connell, J.T., "Ephedrine, Phenylpropanolamine, and Placebo Comparisons," draft of unpublished study (CRD 74–9), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(8) Connell, J.T., "Nasal Airway Flow Rate Measurement Comparisons," draft of unpublished study (CRD 74–57), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(9) doPico, G.A., "Ephedrine and Placebo Comparison," draft of unpublished study (CRD 76–61), in Comment No. C0214, Docket No. 76N–052N, Dockets Management Branch.
(10) McLaurin, J.W., W.F. Shipman, and R. Rosedale, "Oral Decongestants—A Double Blind Comparison Study of the Effectiveness of Four Sympathomimetic Drugs: Objective and Subjective," *Laryngoscope*, 71:54–67, 1961.
(11) Gowen, G.H., and A.J. Nedzel, "Effectiveness of the Oral Administration of Ephedrine in the Common Cold," *Illinois Medical Journal*, 71:132–136, 1937.
(12) Mothersill, M.H., "Treatment of Hay Fever with a Combination of a Sympathomimetic and an Antihistaminic Drug," *Annals of Allergy*, 8:223–228, 1950.
(13) Aschan, G., "Decongestion of Nasal Mucous Membranes by Oral Medication in Acute Rhinitis," *Acta Otolaryng*, 77:433–438, 1974.
(14) Letter from W.E. Gilbertson, FDA, to E.J. Hanus, Richardson-Vicks, coded LET020, Docket No. 76N–052N, Dockets Management Branch.
(15) Letter from W.E. Gilbertson, FDA, to E.J. Hanus, Richardson-Vicks, coded LET107, Docket No. 76N–052N, Dockets Management Branch.

7. One comment submitted a citizen petition requesting that 10 mg menthol in a solid dosage form for use as a topical/inhalant nasal decongestant be included in the final monograph (Refs. 1 and 2). The comment requested the following directions for use for the 10-mg menthol solid dosage form: "Adults and children 3 to under 12 years of age: dissolve one solid dosage form in the mouth every 2 hours as needed. Do not chew. Children under 3 years of age: consult a doctor."

The agency has reviewed the petition and other information and finds the data supportive of the effectiveness of a 10-mg menthol lozenge as a single dose for topical nasal decongestant use. However, the agency has concluded that the data are not sufficient to include the ingredient in the monograph for the reasons discussed below.

The petition included a double-blind, randomized, placebo-controlled, parallel-design, single-dose study of a 10-mg menthol lozenge in subjects with viral rhinitis. The subjects were at least 18 years of age with symptoms of stuffy nose, runny nose, sneezing, and/or cough of no more than 48 hours duration. The objective of the study was to determine if statistically significant decreases in nasal airway resistance occurred at specific intervals after administration of the drug. Posterior rhinometry measurements were correlated with the subjects' subjective ratings of decongestant activity. Measurements of nasal flow/resistance were made 5 min before and immediately prior (0 min) to administration of the test lozenge and at 15, 30, 60, 90, and 120 min after dosing. The measurement immediately prior to dosing was used as the baseline measurement. The nasal/flow resistance data were analyzed by a repeated measures analysis of variance with 6 time points (baseline, 15, 30, 60, 90, and 120 min) as the repeat factor. Changes from the baseline at the post-treatment time points were also analyzed using a one-way analysis of variance.

The agency notes that the protocol for this study is similar to that proposed by the Panel (41 FR 38312 at 38415). The Cough-Cold Panel recommended that a study to show effectiveness of a nasal decongestant drug should be a double-blind, placebo-controlled assessment of the drug's ability to decrease nasal airway resistance. The Cough-Cold Panel also considered subjective assessment by the subjects to be desirable. The Cough-Cold Panel stated that where rebound congestion with repeated use is a concern, labeling should specify short-term use in providing temporary relief of symptoms. The Cough-Cold Panel recommended that specific data be obtained by testing the nasal decongestant in the concentrations and maximal dosage frequencies to be recommended for periods of at least 1 week to address the incidence and severity of a drug-induced increase in nasal airway resistance. The Cough-Cold Panel required two positive studies based on the results of two different investigators or laboratories to show effectiveness.

The agency finds that the results of the study suggest that 10 mg menthol in a solid dosage form is effective in the relief of nasal congestion due to viral rhinitis. However, the repeated measures analysis of variance results were not informative because they

included the baseline levels in the analysis. By deleting the baseline levels from the analysis, the agency notes that the multivariate analyses of the data using the Statistical Analysis System Institute statistical system showed a significant treatment effect but nonsignificant time and treatment by time interaction. The results of the study support a 2-hour duration of action from a single dose. However, because the proposed directions for the product include multiple doses (i.e., "every 2 hours as needed"), another study involving multiple doses is needed to support effectiveness. The study needs to be done using the same dosage with the drug given at the same time intervals as proposed for the label directions. A 3-day study is necessary to show effectiveness as a nasal decongestant if the product will be indicated for colds and 7 days if indicated for allergies.

The agency notes that the petition did not address the potential problem of rebound congestion occurring with repeated use of menthol lozenges. In the tentative final monograph (50 FR 2220 at 2233), the agency discussed the occurrence of rebound congestion resulting from topical nasal decongestants in a lozenge or mouthwash dosage form. The agency stated that when ingredients such as menthol are administered in the form of lozenges, rebound is unlikely to occur and that it may be more appropriate to use a 7-day warning, i.e., "Do not use this product for more than 7 days," rather than a 3-day warning. However, because such lozenges are not included in this final monograph, such a warning requirement is not applicable at this time. The agency believes that the potential for rebound congestion to occur should be studied in any multi-dose study, such as the study discussed above, involving topical nasal decongestants in a lozenge or mouthwash dosage form to rule out the potential for rebound congestion to occur and to determine which warning statement would be appropriate to use for the product.

Based on the above information, the agency is not including 10 mg menthol in solid dosage form as a topical nasal decongestant in this final monograph. The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 3).

References

(1) Comment No. CP00010, Docket No. 76N–052N, Dockets Management Branch.

(2) Letter from C.A. Sloughfy, Jr., Beecham Products, to J.R. Gebert, FDA, coded as LET101, Docket No. 76N–052N, Dockets Management Branch.

(3) Letter from W.E. Gilbertson, FDA, to B. Misek, Beecham Products, coded as LET108, Docket No. 76N–052N, Dockets Management Branch.

8. One comment objected to the agency's proposal in the tentative final monograph to restrict to professional labeling the use of oxymetazoline hydrochloride in children under 6 years of age because this action would exclude such use from general consumer labeling. Referring to studies that showed substantial differences when oxymetazoline was given to dogs intranasally and intravenously to elicit a cardiovascular effect (i.e., increase in blood pressure), the comment stated that the amount of oxymetazoline required to elicit any systemic effect by the intranasal route would be virtually unachievable with marketed products. Thus, according to the comment, it would be extremely unlikely that a child could receive a dose of oxymetazoline that would have systemic effects. In addition, the comment stated that a review of the company's adverse experience files showed no cardiovascular side effects from oxymetazoline that were not associated with significant overuse (either in frequency of use, quantity of use, or both). The comment added that a tabulation of the company's and FDA's adverse reaction files for oxymetazoline for the period 1975 to 1989 showed only three cases of adverse reactions in children. The comment stated that the scarcity of adverse reaction experiences demonstrates that there is no safety problem. Further, the comment contended that limiting pediatric formulations (0.025 percent) of oxymetazoline to professional labeling (excluding use from consumer labeling) is inappropriate because an OTC drug must first be available to consumers with proper labeling before professional labeling can apply. The comment contended that the agency's justification for placing 0.025 percent oxymetazoline in professional labeling, i.e., that there is a theoretical possibility of a young child swallowing excessive amounts of a potent long-acting drug due to difficulty in administering accurate dosages, is unfounded. The comment stated that if this problem does exist, it would also be a problem with the shorter acting topically applied nasal decongestant drug products because these shorter acting drug products are administered more often. If this is the case, according to the comment, then the shorter acting drug products labeled for use in young children should be labeled with the same age restrictions as proposed for oxymetazoline.

With respect to the agency's concern that it is difficult to measure the correct dose in a small child and that the child may receive an excessive dose by swallowing the administered medication (50 FR 2220 at 2230), the comment contended that drops are more easily administered than sprays. The comment stated that drops are sufficiently accurate to assure safe use in children and that, to the best of its knowledge, all pediatric formulations (0.025 percent) of oxymetazoline are marketed for use as drops, not sprays. The comment noted, specifically, that the orifice of the dropper of its oxymetazoline pediatric nasal drops drug product is controlled so that it consistently delivers an average drop volume of 0.028±0.008 mL. The comment argued that this additional safety feature further assures the accuracy of the dose. The comment concluded that it is extremely unlikely that a child could receive a dose of oxymetazoline that would have a systemic effect, even if the child inadvertently swallowed some of the drops.

The comment maintained that restricting pediatric use of oxymetazoline to professional labeling will not ease the task of measuring a correct dose, nor will it cause a young child to swallow any less of a nasal solution than he/she otherwise would. The comment contended that dosing concerns can be addressed by consumer labeling. For example, instructions for use in children might include a provision that if less than a full dose is delivered on the first try, no further attempt to readminister the drug should be made. Additionally, an alternative safeguard could be provided by restricting the amount of drug that a dropper can deliver, i.e., a safety dropper can be designed to deliver approximately 6 drops which corresponds to the labeled maximum dose of 3 drops in each nostril under conditions of normal use. The comment concluded that the agency should accept the Panel's recommendation to permit consumer labeling for oxymetazoline for children 2 to under 6 years of age.

The agency has reviewed its adverse reaction reports for oxymetazoline covering the period from 1969 to the present (Ref. 1). Only five adverse reactions in children under 8 years of age have been reported. Six adverse reactions involving xylometazoline in children under 8 years of age have been reported to the agency since 1970 (Ref.

2). Except for a single death (without sufficient detail to attribute cause in a 3-month-old male who presented a history consistent with sudden infant death syndrome), all affected children recovered soon after discontinuation of the medication. The reported reactions are generally of expected events (i.e., excitation, agitation) or involve concomitant medications associated with the reactions (e.g., antihistamines and sleepiness, or a previous history of rash from an antibiotic). Considering the long marketing history and the extent of the use of topical oxymetazoline and xylometazoline, the agency considers the number and severity of the reported cases to be very low.

Biesalski and Marquart (Ref. 3) evaluated the nasal decongestant effect of xylometazoline hydrochloride (0.1 and 0.01 percent) in 72 infants aged 5 days to 14 months, 3 premature infants, and 42 children. An additional group of 48 infants was given xylometazoline in concentrations ranging from 0.0005 to 0.005 percent. The investigators measured blood pressure in 11 children and monitored cardiac activity in 69 infants and found no effects caused by the drug. Four infants with congenital heart defects had no side effects on the heart or circulation from the drug. The investigators stated, "No side effects of any kind were noted, even in premature infants or in infants with cardiac conditions."

Based on this safety profile and the ability to control the amount of drug administered per drop or spray, the agency concludes that limiting information on the topical use of oxymetazoline and xylometazoline in children 2 to under 6 years of age to professional labeling only is unwarranted. This type of limitation would not eliminate the dangers of misuse and overuse in this age group. The agency agrees with the comment that the risk of overdose or misuse can be adequately handled by the use of a dropper or spray that is designed to restrict the amount of drug delivered to a maximum allowable dose and by appropriate OTC labeling directions and warnings.

The United States Pharmacopeia discusses calibrated dropper specifications where accuracy of dosage is important. The volume error incurred in measuring any liquid by means of a calibrated dropper should not exceed 15 percent under normal use conditions (Ref. 4). The agency is incorporating this standard for a calibrated dropper in the final monograph. The agency believes that this criterion will help assure an accurate dose and minimize the risk of overdose.

To further emphasize to consumers the importance of proper administration and the dangers of overdose in children in this age group, the agency is incorporating the following statement in the directions: "Use only recommended amount." The agency recognizes that the warnings for these two drugs already include the statement "Do not exceed recommended dosage." Nonetheless, the agency believes that an additional statement in the directions sections will reinforce the importance of not using an excessive amount of drug. The agency also believes that the warning not to exceed the recommended doses within a 24-hour period will provide an additional safeguard against overdosing. The agency is requiring that both of these statements appear in product labeling in boldface type.

Accordingly, the agency is adding new sections for oxymetazoline hydrochloride (§ 341.80(d)(2)(iv)(A)(*2*)) and xylometazoline hydrochloride (§ 341.80(d)(2)(vii)(A)(*2*)). The agency is requiring that pediatric products be marketed in a container with a controlled, metered-dose children's safety dropper or spray that is calibrated to deliver no more than a maximum allowable dose. Based on the information on the controlled dropper provided by the comment, which is the manufacturer of the major marketed OTC oxymetazoline pediatric nose drop products, the following doses are being included in this final monograph.

For oxymetazoline hydrochloride, the product must have either a calibrated dropper or a metered-dose spray that delivers no more than 0.027 mg of oxymetazoline hydrochloride per three drops or three sprays. The directions for use are to include the following information: Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril of a 0.025-percent aqueous solution not more often than every 10 to 12 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

For xylometazoline hydrochloride, the product must have either a calibrated dropper or metered-dose spray that delivers no more than 0.054 mg of xylometazoline hydrochloride per three drops or three sprays. The directions for use are to include the following information: Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril of a 0.05-percent aqueous solution not more often than every 8 to 10 hours. Use only recommended amount. Do not exceed 3 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

Phenylephrine 0.125 percent aqueous solution is the only other OTC topical nasal decongestant labeled for use by children 2 to under 6 years of age. The agency believes that products containing this drug should also have a calibrated dropper or a metered-dose spray. Using the same standard as above, the product must have either a calibrated dropper or metered-dose spray that delivers no more than 0.135 mg per three drops or three sprays. Similarly, the directions for use are to include the following statement: "Use only recommended amount."

If manufacturers have information that demonstrates that an amount of drug different than those listed above for three drops or sprays of oxymetazoline hydrochloride, xylometazoline hydrochloride, and phenylephrine hydrochloride, the agency will evaluate that information and determine if the above standards should be changed. Manufacturers should submit the information in a citizen petition in accord with § 10.30 (21 CFR 10.30).

References

(1) Department of Health and Human Services, Food and Drug Administration, "Spontaneous Reporting System, Line Listing of Adverse Reports," 1969–1993.

(2) Department of Health and Human Services, Food and Drug Administration, "Spontaneous Reporting System, Line Listing of Adverse Reports," 1970–1993.

(3) Biesalski, P., and K. Marquart, "Therapeutic Aspects of Rhinitis in Early Childhood, Thermoelectrode Investigations with Nasal Decongestants" ("Zur Behandlungder Rhinitis im fruhen Kindesalter. Thermoelektrische Untersuchungen an abschwellenden Nasenmittein") (English Translation), *Schweizerische Medizinische Wochenschrift*, 89(19):510–512, 1959.

(4) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1684, 1989.

9. One comment requested that the status of phenylephrine bitartrate be clarified in the final monograph. The comment stated that data were submitted to the Cough-Cold Panel indicating that phenylephrine bitartrate, while not as commonly used as the hydrochloride salt of phenylephrine, had the same characteristics (Refs. 1 and 2). The comment noted that the proposed dose of phenylephrine hydrochloride in adults is 10 mg which is equivalent to approximately 15.5 mg of phenylephrine bitartrate. Stating that the noninclusion of phenylephrine bitartrate in the Cough-Cold Panel's

report and the tentative final monograph appeared to be an inadvertent omission, the comment requested that phenylephrine bitartrate be classified as a Category I oral nasal decongestant.

The agency acknowledges that phenylephrine bitartrate was submitted as an oral nasal decongestant active ingredient in an effervescent combination cold tablet for OTC use containing 7.8 mg phenylephrine bitartrate (4.1 mg phenylephrine base) which is present in the same amount in solution for oral use. The maximum recommended dose is 8 tablets in 24 hours. Therefore, the maximum dose of phenylephrine bitartrate would be 62.4 mg (32.8 mg phenylephrine base) per day (Ref. 1). However, the ingredient apparently was not reviewed by the Cough-Cold Panel or included in its report, or addressed in the tentative final monograph for OTC nasal decongestant drug products. The agency has reviewed the submitted data and notes that the submission (Ref. 1) states that the Physicians' Desk Reference, 1972 edition, lists two products containing phenylephrine bitartrate (Ref. 3). The agency has determined that these two products are aerosol inhalation devices which deliver micronized particles of isoproterenol hydrochloride and phenylephrine bitartrate for inhalation by mouth into the bronchial tree. The products have the following indications: (1) Acute bronchial asthma and other allergic states, and (2) chronic obstructive pulmonary diseases such as chronic bronchitis and pulmonary emphysema (Ref. 3).

The submission also includes an acute oral toxicity study conducted on phenylephrine bitartrate, chlorpheniramine maleate, and phenylephrine hydrochloride as individual active ingredients. The acute oral LD_{50} for phenylephrine bitartrate alone is presented as 170.7 ± 17.0 mg per kilogram (kg); that for phenylephrine hydrochloride alone is presented as 61.3 ± 11.6 mg/kg (Refs. 1 and 2). In addition, the submission includes a bioavailability (blood level) study of phenylephrine bitartrate combined in an effervescent cold tablet with aspirin and chlorpheniramine maleate (Ref. 2). The study compares phenylephrine plasma levels obtained for three combination drug products containing the following active ingredients: (1) Aspirin, phenylephrine bitartrate (7.1 mg), and chlorpheniramine maleate, (2) aspirin, phenylephrine hydrochloride (5 mg), phenindamine tartrate, and caffeine, and (3) phenylephrine hydrochloride (20 mg) and chlorpheniramine maleate. Although comparable plasma levels of phenylephrine were obtained with the first and second test formulations, the agency has determined that these bioavailability studies do not demonstrate effectiveness because the claimed pharmacological effectiveness of OTC drug monograph active ingredients must be established by controlled clinical investigations (21 CFR 330.10(a)(4)(ii)). No clinical data were submitted to show the effectiveness of phenylephrine bitartrate as an oral nasal decongestant. Moreover, the agency has conducted an extensive literature search and is unaware of any data or information in the scientific literature regarding the use of phenylephrine bitartrate as an oral nasal decongestant active ingredient. The products containing phenylephrine bitartrate that were cited by the comment (Refs. 1 and 3) are aerosol products administered by inhalation and are not indicated for nasal decongestant use. Further, the submitted product has been reformulated and no longer contains phenylephrine bitartrate (Ref. 4). The agency concludes that the data are inadequate to generally recognize phenylephrine bitartrate as safe and effective as an oral nasal decongestant, and this ingredient is not being included in the final monograph for OTC nasal decongestant drug products.

References

(1) OTC Vol. 040192.
(2) OTC Vol. 040193.
(3) "Physicians' Desk Reference—1972," 26th ed., Medical Economics, Inc., Oradell, NJ, pp. 1102 and 1105, 1972.
(4) Letter from B.S. Shuster, Miles Laboratories, Inc., to G. Kerner, FDA, dated April 24, 1987, in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

10. One comment requested that a product containing phenol 1.56 percent, thymol, sodium perborate, methyl salicylate, alum powder, sage, and honey, used as a spray, atomizer, swab, or gargle, be considered in the nasal decongestant drug products rulemaking. The labeling claim for the product is for "hygienic care of * * * nasal passages" (Ref. 1). In a followup communication with the agency, the comment clarified that phenol is the only active ingredient in the product (Ref. 2).

No data on the use of 1.5 percent phenol for "hygienic care of nasal passages" were submitted to the Cough-Cold Panel following the "call-for-data" notice that was published in the **Federal Register** of August 9, 1972 (37 FR 16029), requesting data on any active ingredients in OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. Nor were any data on phenol for this use submitted to the agency for inclusion in the tentative final monograph for OTC nasal decongestant drug products published in the **Federal Register** of January 15, 1985 (50 FR 2220). Thus, neither the Cough-Cold Panel in its report (41 FR 38312), nor the agency in its tentative final monograph, considered this ingredient or claim for topically applied nasal drugs in the rulemaking for OTC nasal decongestant drug products. The comment did not submit any data to demonstrate the safety and effectiveness of the claimed active ingredient, phenol, in the nasal passages or to substantiate the claim it requested for this ingredient. Nevertheless, the agency has evaluated the claim "hygienic care of nasal passages" and considers this claim to be vague and meaningless because it does not describe any therapeutic benefits to be obtained from use of the product. Thus, the agency concludes that phenol as an active ingredient and labeling for its use "for hygienic care of nasal passages" are nonmonograph conditions.

References

(1) OTC Vol. 160233.
(2) Telephone communications between A. Horn, co-owner of marketing rights for Formula U, and M. Benson, FDA, March 21 and March 30, 1984, in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

D. Comments on Dosages for OTC Nasal Decongestant Active Ingredients

11. In response to the agency's proposal (50 FR 2220 at 2229 to 2230) that pseudoephedrine preparations be available at dosage levels twice those previously permitted for OTC use, i.e., 60 mg instead of 30 mg, one comment expressed a hope that pseudoephedrine would continue to be available in 30 mg tablet strength, or if in 60 mg strength, that tablets will be scored for breaking.

The final monograph does not address tablet characteristics such as shape, size, scoring, etc. However, manufacturers must provide consumers with dosage forms and strengths that are consistent with the dosages and directions for use in OTC drug monographs. The adult dosage for products containing pseudoephedrine is 60 mg every 4 to 6 hours. Manufacturers may market a 60-mg product with a one-tablet dosage or a 30-mg product with a two-tablet dosage. The pseudoephedrine dosage for children 6 to under 12 years of age is 30 mg every 4 to 6 hours. Thus, it is reasonable to expect that 30 mg tablets of pseudoephedrine will continue to be available.

12. Several comments recommended that the agency consider new weight-based/age-related pediatric dosing schedules for cough-cold drug products (including nasal decongestants) based on a pediatric dosing unit (PDU) concept that provides for additional age groupings developed to better meet the needs of the growing pediatric patient. Some comments suggested that the Cough-Cold Panel's recommended pediatric dosing schedule of 6 to under 12 years and 2 to under 6 years be replaced with the PDU concept that would utilize a pediatric dosage schedule equivalent to 1/8 the adult dose and include additional age breaks (i.e., 2–3, 4–5, 6–8, 9–10, and 11 years) and/or weight groupings (i.e., 24–35, 36–47, 48–59, 60–71, and 72–95 pounds). Other comments also recommended that this new pediatric dosing schedule be optional. For products targeted primarily for adults, which also incorporate some dosage recommendations for pediatric use, the comments felt that it was reasonable to continue to use the dosing schedule proposed in the tentative final monograph. But for products primarily intended for pediatric use, the comments felt that there was a need for incremental dosing throughout the entire pediatric (under 12 years) age range consistent with the incremental age and weight ranges within the typical growth patterns in children. Stating that the pediatric dosage of cough-cold drug products should be reconciled with the dosage schedules recommended by the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel) (42 FR 35346 at 35489 to 35491, July 8, 1977, which includes additional age groupings), two comments contended that such a change would provide consistency between the various monographs and allow for consistency in the formulation of combination drug products containing a nasal decongestant and an analgesic-antipyretic.

Two comments also recommended that the agency add a professional dosing schedule for children under 2 years of age, based on the PDU concept. As an example, one comment suggested that the professional labeling section for oral pseudoephedrine be amended to include the following: Children 1 year of age, 11.25 mg every 4 to 6 hours, not to exceed 45 mg in 24 hours; children 4 months to under 1 year, 7.5 mg every 4 to 6 hours, not to exceed 30 mg in 24 hours.

Because a number of OTC drug rulemakings could be affected if pediatric dosages are revised as requested by the comments, the agency has published a separate document in the **Federal Register** that discusses pediatric dosages for OTC drug products. Therefore, comments regarding a weight-based, age-related pediatric dosage schedule for pseudoephedrine and other oral nasal decongestants are being deferred at this time and have been addressed in a separate notice entitled "Pediatric Dosing Information for OTC Human Drugs; Intent and Request for Information," published in the **Federal Register** on June 20, 1988 (53 FR 23180). Should pediatric dosage schedules, in general, be revised in the future, the final monograph for OTC nasal decongestant drug products will be amended accordingly.

E. Comments on Labeling of OTC Nasal Decongestant Drug Products

13. Two comments stated that FDA lacks statutory authority to prescribe exclusive lists of terms from which indications for use for OTC drug products must be drawn and to prohibit alternative labeling terminology which is truthful, accurate, not misleading, and intelligible to the consumer. One comment recommended that, instead of prohibiting the use of alternative truthful terminology, FDA should permit manufacturers to choose consumer oriented language to communicate the desired label indications, so long as such language is not false or misleading. Both comments noted that FDA had proposed certain revisions to the "Exclusivity Policy" on April 22, 1985 (50 FR 15810) and stated that they would be submitting further comments on that proposal.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either: (1) The specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "approved uses"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "approved uses"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "approved uses," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In the tentative final monograph for OTC nasal decongestant drug products (50 FR 2220 at 2238), supplemental language relating to indications had been proposed and captioned as "Other allowable indications." Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under that monograph. (See comment 16 in section I.E. of this document.)

14. Four comments requested that § 341.80(b) of the tentative final monograph be amended to allow manufacturers to choose from among any of three basic indications provided, i.e., the common cold (cold), allergy, or sinusitis. The comments contended that the intended target populations for products promoted and marketed for treating the common cold, allergy, and sinusitis are different and that specific products should be allowed to be designed or positioned for specific consumer populations. One comment pointed out that the use of all three indications for all products containing oral nasal decongestants, as proposed in § 341.80(b), may not only be extraneous, but potentially confusing to consumers. Two comments provided examples of how this labeling could be extraneous: (1) Indications for hay fever or allergic rhinitis would be inappropriate on a product marketed as a "cold" product, and (2) indications for a cold would be inappropriate for persons suffering from allergy or sinusitis. One comment added that small packages of multi-ingredient combination products contain little label space for necessary indications and warnings. It is therefore important for the distributor of a product to have the option to eliminate indications which are not applicable to a particular segment of the market for which the product is positioned.

The comments requested, therefore, that the indications in § 341.80(b) be amended to allow manufacturers to choose from among any of the basic indications (i.e., the common cold (cold), allergy, or sinusitis) that are appropriate for the consumer market segment to which the product is directed. One comment suggested that § 341.80(b)(1) be modified to read as follows:

> The labeling of the product contains a statement of the indications under the heading "Indications" which includes one or more of the following indications: "For the temporary relief of nasal congestion due to" (select one of the following) "the common cold (cold)," "hay fever (allergic rhinitis)," or "associated with sinusitis."

The agency agrees with the comments that manufacturers should be allowed to choose from among any of the indications proposed for nasal decongestant drug products in § 341.80(b)(1) that are consistent with the intended use of the product.

Thus, in this final monograph the agency is revising the "Indications" in § 341.80(b)(1), to read as follows: (Select one of the following: "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion") (which may be followed by any of the following in (i), (ii), and (iii) below):

(i) "due to" (select one of the following: "the common cold" or "a cold").

(ii) "due to" (select one of the following: "hay fever," "hay fever (allergic rhinitis)," "hay fever or other upper respiratory allergies," or "hay fever or other upper respiratory allergies (allergic rhinitis)").

(iii) "associated with sinusitis."

15. With regard to the indications proposed in § 341.80(b), two comments stated that the phrases "for the temporary relief of" and "temporarily relieves" are similar and should be interchangeable.

The agency agrees with the comments that the phrases are interchangeable. Therefore, the agency has included the option of using either phrase in the indications included in § 341.80(b) of this final monograph. (See comments 14 and 16 in section I.E. of this document.)

16. One comment requested that the "other allowable indications" proposed in § 341.80(b)(2) of the tentative final monograph be alternative statements rather than additional statements to the indications proposed in § 341.80(b)(1). The comment contended that this would permit meaningful alternate "consumer oriented" label indications. Another comment assumed that the "other allowable indications" proposed in § 341.80(b)(2) may be identified on product labels as "other indications" if they are separate from the indications identified in § 341.80(b)(1) and are not given greater prominence.

In this final monograph, the agency is revising the indications in § 341.80(b)(1) to allow manufacturers the option of using one or more of the indications (see comment 14 in section I.E. of this document.) The agency considers the required indication statement(s) essential in providing adequate and informative labeling to the consumer. Under the agency's revised labeling policy for OTC drug products, discussed in comment 13 in section I.E. of this document, the "other allowable indications" that were proposed in § 341.80(b)(2) of the tentative final monograph have been included in the final monograph as part of the indications in § 341.80(b). However, the agency does not consider the text of these "other allowable" indication statements as providing complete information that is comparable to the information contained in § 341.80(b)(1). Because they provide additional, complementary information, the previous "other allowable" indications are included in § 341.80(b)(2) of the final monograph as statements that may appear in the "APPROVED USES" boxed area in the labeling, in addition to one or more of the indications in § 341.80(b)(1).

Therefore, the labeling of the product may contain any (one or more) of the following statements, which appear in § 341.80(b)(2) of this final monograph, provided the required information identified in § 341.80(b)(1) (see comment 14 in section I.E. of this document) is also included:

(i) (Select one of the following: "For the temporary relief of" or "Temporarily relieves") (select one of the following: "stuffy nose," "stopped up nose," "nasal stuffiness," or "clogged up nose.")

(ii) (Select one of the following: "Reduces swelling of," "Decongests," or "Helps clear") "nasal passages; shrinks swollen membranes."

(iii) "Temporarily restores freer breathing through the nose."

(iv) "Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure."

(v) "Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure."

(See also comment 17 in section I.E. of this document.)

17. One comment requested modification of the "other allowable indications" for nasal decongestant drug products in proposed § 341.80(b)(2)(i) to include the terms "stuffed-up head" and "stuffy head" as follows: "For the temporary relief of (select one of the following): stuffy nose, stopped-up nose, nasal stuffiness, clogged-up nose, stuffed-up head, stuffy head."

The agency does not consider the terms "stuffed-up head" and "stuffy head" specific enough to be included in this final monograph. The agency believes that other terms could be used in the indication statements to provide more specific information to consumers about the action of this type of drug product than the comment's suggestion of the general terms "stuffed up head" and "stuffy head." In the tentative final monograph, the agency included "relieves sinus pressure" as a Category I indication for nasal decongestants (50 FR 2220 at 2231). Sinus pressure and sinus congestion are closely associated and if congestion is relieved, pressure also would be relieved (50 FR 2220 at 2232). Therefore, in this final monograph, the agency is including the term "sinus congestion" in the indications in § 341.80(b)(2)(iv) and (b)(2)(v). The agency concludes that the terms "sinus congestion" and "sinus pressure" provide more specific information than the comment's suggested terms. In addition, the agency is including these terms in § 341.80(b)(2)(iv) and (b)(2)(v) because those paragraphs primarily deal with "sinus" conditions, whereas the indication in § 341.80(b)(2)(i) primarily deals with "nose" conditions. (See comment 16 in section I.E. of this document for additional discussion of the other indications included in this final monograph.)

However, as discussed in comment 13 in section I.E. of this document, the agency has revised its labeling policy for OTC drug products. FDA has found that it simply is not practical—in terms of time, resources, and other considerations—to set standards for all labeling found in OTC drug products. Accordingly, OTC drug monographs directly address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. These labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action. Truthful and nonmisleading terms that provide additional information about an OTC drug product but are not directly related to its safe and effective use are considered outside the scope of the OTC drug review and may appear elsewhere in the labeling,

separate from the monograph approved statements. Thus, because consumers are familiar with and use terms such as "stuffed-up head" and "stuffy head," the agency considers these terms as acceptable to be included elsewhere in the labeling (but such terms may not be intermixed with any portion of the labeling required by the monograph and may not detract from such required information). Terms outside the scope of the review will be evaluated by the agency on a product-by-product basis, under the provision of section 502 of the act relating to labeling that is false or misleading.

18. One comment requested that the indication, "helps (select one of the following: relieve, alleviate, decrease, reduce) post-nasal drip" be added as an additional consumer claim for nasal decongestant drug products.

The Cough-Cold Panel placed a similar claim, "checking post-nasal drip," in Category III because such claims are unsubstantiated for nasal decongestants unless studies specifically designed to assess "post-nasal drip" are presented. The Cough-Cold Panel stated in 41 FR 38415 that studies of nasal decongestants have assessed the effect of nasal airway resistance or the ease of breathing but not the effect on rhinorrhea that causes post-nasal drip. The comment did not submit any data concerning the effect of nasal decongestants on rhinorrhea that would support a claim for "post-nasal drip."

Further, the agency is unaware of any data to support consumer recognition of an indication regarding post-nasal drip. The agency reviewed information submitted to the antihistamine final monograph rulemaking requesting an indication for "post- nasal drip." The comment asserted that substantial numbers of consumers recognize that relief of "post-nasal drip" is a desirable end benefit and that consumers clearly understand the term "post-nasal drip." The comment provided two consumer mail panel studies, which were designed to investigate consumer attitudes towards, and usage of, sinus and hay fever remedies. The comment stated that of the 263 responding sinus sufferers, 49 percent (129) considered relief of post-nasal drip important when choosing a sinus remedy. Similarly, 48 percent (119) of the 248 hay fever respondents indicated that relief of post nasal drip was important when choosing a hay fever product. The agency's review of the studies disclosed that they were not designed to demonstrate the effectiveness of OTC antihistamine drug products in relieving the symptom "post-nasal drip" or provide a basis for a "post-nasal drip" indication. These data, therefore, are not useful in supporting a "post-nasal drip" indication for nasal decongestant or antihistamine drug products.

Clinical studies specifically designed to demonstrate the effectiveness of nasal decongestants in relieving "post-nasal drip" would be necessary before this claim could be used in the labeling of any nasal decongestant drug product. Such studies should be designed to evaluate the symptom of "post-nasal drip" in terms of specific symptoms that can be recognized by consumers as "post-nasal drip." The agency suggests that any party interested in studying the use of a nasal decongestant for this claim meet with the agency to discuss an appropriate protocol before beginning the study. For the above reasons, indications pertaining to "post-nasal drip" are not being included in this final monograph for OTC nasal decongestant drug products.

19. Two comments stated that the agency should differentiate between "Warnings" and "Cautions" in OTC drug labeling, and one comment objected to the proposed elimination of the term "Caution(s)" in the labeling of OTC drug products. The comments contended that "Warnings" are harsher (stronger) and more serious than "Cautions" and even preclude use of a product under certain conditions. One comment stated that a "Caution," on the other hand, does not preclude use unless something occurs during use, but it often alerts the consumer to a potential problem. The comment added that a caution may also address a monitoring function to be performed while the product is in use. The second comment stated that a caution should be used to convey important information related to the safe and effective use of the product, but allow for judgment on the part of the user, e.g., "This product may cause drowsiness." The comment felt that the importance of the "Warnings" section was undermined if it contains too much information or if it includes less than serious language. The comment provided several examples of the differences between warnings and cautions and suggested that the agency also consider the term "precautions."

Section 502(f)(2) of the act states, in part, that any drug marketed OTC must bear in labeling "* * * such adequate warnings * * * as are necessary for the protection of users * * *." Section 330.10(a)(4)(v) of the OTC drug regulations provides that labeling of OTC drug products should include "* * * warnings against unsafe use, side effects, and adverse reactions * * *."

The agency notes that historically there has not been consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in §§ 369.20 and 369.21 (21 CFR 369.20 and 369.21), which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances, either of these signal words is used to convey the same or similar precautionary information. In addition, the term "precaution(s)," as in "Drug Interaction Precaution(s)" is often used in OTC drug monographs, but is listed under "Warnings" as, for example, in the rulemakings for OTC nasal decongestant drug products and OTC bronchodilator drug products. (See the Federal Register of January 15, 1985 (50 FR 2220 at 2239) and October 2, 1986 (51 FR 35326 at 35339), respectively.)

FDA has considered which of these signal words would be most likely to attract consumers' attention to that information describing conditions under which the drug product should not be used or its use should be discontinued. The agency concludes that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. The agency is not convinced that consumers will make the distinctions between "warnings" and "cautions" that the comments have made. Further, the agency does not believe that the importance of the "Warnings" section will be undermined if all of the information about unsafe use, side effects, and adverse reactions is presented under a single heading. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems. However, except in instances where the agency has stated that a particular warning statement must appear as the first warning after the "Warnings" heading, the agency has no objections if manufacturers list the various warnings statements in their order of preference, e.g., listing first those they consider more serious followed by those they consider to be less serious statements. Drug interaction precaution information will continue to be listed under the heading "Drug Interaction Precautions" as part of the warnings information.

20. One comment stated that it is difficult to read labels of nasal decongestant drug products because the containers are small and the print on the labels also is small. The comment was particularly concerned that the required warnings would not be legible and

recommended that the warnings should be "clearly, in sizable print, be evident, but only a minimum amount." The comment stated that it would be more useful if "warning sheets" or booklets were available with nasal decongestant packages. A second comment requested larger print size and more prominent location of warnings on nasal decongestant products.

In the tentative final monograph for OTC nasal decongestant drug products (50 FR 2220), the agency simplified or revised several and deleted some of the warnings recommended by the Cough-Cold Panel. (See comments 13, 21, 24, 26, 28, and 29 in the tentative final monograph.) The agency believes that the labeling proposed in this final monograph includes only essential information that is necessary to assure proper and safe use of OTC nasal decongestant drug products by consumers. Moreover, the labeling of drugs must comply with section 502(c) of the act which states that a drug shall be deemed to be misbranded:

> If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

In general, a product container label needs to bear the following information: A statement of ingredients (section 502(e) of the act), name and address of the manufacturer, repacker, or distributor (section 502(b)(1) of the act), a net contents statement (section 502(b)(2) of the act), a lot number (21 CFR 201.18), and an expiration date (21 CFR 201.17). In some situations, other labeling information is required to appear on the immediate container labeling, e.g., the Reye syndrome warning for drug products containing salicylates (21 CFR 201.314).

When an OTC drug product is packaged in a container that is too small to contain all the required labeling, the agency recommends that the product be enclosed in a carton or be accompanied by a package insert or booklet that contains the information complying with the monograph. Manufacturers are also encouraged to print a statement on the product container label, carton, or package insert suggesting that the consumer retain the carton or package insert for complete information about the use of the product when all the required labeling does not appear on the product container label. Manufacturers who use supplemental labeling should be able to readily provide all labeling information in a larger print size than if all of the labeling is presented on the immediate container. Further, the agency is aware that many manufacturers use bold lettering and a colored label to emphasize certain labeling information, including warnings, on the immediate container and in package inserts. All manufacturers are encouraged to use these as appropriate to highlight and emphasize certain labeling information for the consumers. The agency previously published a request for public comment (56 FR 9363 to 9365, March 6, 1991) on the issue of print size and style of labeling for OTC drug products, and will evaluate comments received before making a final decision on the feasibility of establishing a Federal regulation pertaining to print size and style of OTC labeling.

The Nonprescription Drug Manufacturers Association (NDMA) has recently promulgated guidelines for industry to consider when examining product labels for readability and legibility (Ref. 1). These guidelines are designed to assist manufacturers in making the labels of OTC drug products as legible as possible. The agency commends this voluntary effort and urges all OTC drug manufacturers to examine their product labels for legibility.

Reference

(1) "Label Readability Guidelines," The Nonprescription Drug Manufacturers Association, Washington, copy included in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

21. Two comments pointed out that the warning for oral nasal decongestants in proposed § 341.80(c)(1)(i)(*b*) (which states: "Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a doctor.") and a similar warning for children in § 341.80(c)(1)(ii)(*b*), could be read to warn against the use of Category I OTC oral nasal decongestant drug products without first consulting a doctor if a fever is present initially. The comments stated that in the advance notice of proposed rulemaking for OTC internal analgesic-antipyretic drug products, the Internal Analgesic Panel classified as Category I the combinations of one or two Category I analgesic-antipyretic active ingredients "* * * with generally recognized as safe and effective nasal decongestant active ingredient(s) provided the product is labeled for the concurrent symptoms involved, * * * for the reduction of fever, * * * " (42 FR 35370, July 8, 1977). One comment contended that while the proposed warning may have limited significance for single ingredient nasal decongestant drug products, it would have a serious and unwarranted adverse effect on the use of combination drug products containing a nasal decongestant along with an analgesic-antipyretic. The comment urged that the proposed warning be reworded to explicitly permit use of a combination product containing an oral nasal decongestant and an antipyretic agent(s) when concurrent symptoms of nasal congestion and fever are present.

The second comment stated that billions of doses of oral nasal decongestants have been used OTC for many years without such a label warning. The comment added that it was unaware of any safety problems that have occurred as a direct consequence of a consumer using a nasal decongestant in the presence of minor fever of short duration, which is the case in the vast majority of instances in which fever is present. On the other hand, the comment contended, the presence of high fever is of importance to the well-being of the consumer, and a doctor should be consulted if such occurs. The comment requested that the above-referenced warnings be amended to read: "(*b*) If symptoms do not improve in 7 days or are accompanied by high fever, consult a doctor."

The comment also stated that some allergic episodes (and even colds) occasionally continue for more than 7 days, particularly in humid climates or in periods of high pollen counts. Therefore, an absolute 7-day use limitation may not always be appropriate. Moreover, the comment stated that its amended warning would be equally informative to consumers who may be taking an oral nasal decongestant product without an antipyretic ingredient as well as to those who may take a combination which includes antipyretic ingredient(s). Thus, the comment requested that this amended warning be included in the following final monographs: (1) OTC nasal decongestant drug products; (2) OTC internal analgesic-antipyretic drug products; and (3) OTC cough-cold combination drug products.

The Cough-Cold Panel noted that a slight fever may be present with the common cold (41 FR 38312 at 38321). The Internal Analgesic Panel stated that antipyretics (fever reducers) may be safely used for self-medication when fever is due to the common cold or flu (42 FR 35346 at 35351). The warnings in § 341.80(c)(1)(i)(*b*) and (c)(1)(ii)(*b*) are not meant to restrict use of an oral nasal decongestant in the presence of minor

fever of short duration such as that which might be associated with a common cold. The agency agrees that a nasal decongestant can be used in such situations. The intent of the warnings is to alert consumers that the presence of a fever might indicate a more serious condition, such as a secondary bacterial infection, for which a doctor should be consulted. For example, a nasal obstruction accompanying a common cold can result in a middle ear infection (acute otitis media). Usually, the first complaint of a middle ear infection is a persistent, severe earache. Other symptoms, such as fever, nausea, vomiting, and diarrhea may occur in young children (Ref. 1). Pneumonia is also often preceded by an upper respiratory infection. Symptoms include chills, sharp pain in the chest, cough, fever, and headache (Ref. 2). Thus, because the agency believes that it is important for consumers to recognize that all fevers are not insignificant occurrences, the word "fever" as proposed in the tentative final monograph is being retained in this final monograph.

This warning for oral nasal decongestant drug products is consistent with the warning included in the final monographs for single ingredient antitussive drug products and single ingredient expectorant drug products, which states: "* * * If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor." (See §§ 341.74(c)(1) and 341.78(c)(2)). These warnings are not meant to restrict the use of an antitussive or an expectorant in the presence of minor fever of short duration such as that which might be associated with a common cold. However, as with the warning for nasal decongestants, the intent of the warnings is to alert consumers that the presence of a fever might indicate a more serious condition, and a doctor should be consulted.

The agency has previously considered inclusion of the word "high" (in reference to fever) in this warning in the final monograph for OTC antitussive drug products. (See 52 FR 30042 at 30054, August 12, 1987.) In that proceeding, the agency determined that the word "high" would not be included in the warning because it is important for the consumer to recognize the presence of fever regardless of whether the fever is high or low. The agency concludes that this principle is equally applicable to the labeling of OTC nasal decongestant drug products. Therefore, the agency is not adopting the second comment's suggested wording related to the use of the term "high" to describe fever.

The agency agrees with the comment that an absolute 7-day limitation may not always be appropriate for oral nasal decongestant drug products. Further, the final monographs for OTC antitussive and expectorant drug products (21 CFR part 341) do not impose a 7-day use limitation, and the agency concludes that such a limitation is also not necessary for oral nasal decongestant drug products. Therefore, the warnings proposed in § 341.80(c)(1)(i)(*b*) and (c)(1)(ii)(*b*) in the tentative final monograph are revised as follows: "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor." These warnings appear in § 341.80(c)(1)(i)(B) and (c)(1)(ii)(B) of this final monograph.

With regard to labeling of cough-cold combination drug products for which the labeling in the individual applicable monographs conflicts or is inappropriate, the agency has proposed specific labeling in § 341.85 of the tentative final monograph for OTC cough-cold combination drug products. (See 53 FR 30522 at 30562 to 30564.) The antipyretic ingredient in an oral nasal decongestant-analgesic-antipyretic combination drug product would be used specifically to treat a fever. Normally, the labeling for such a product would contain the appropriate portions of the monograph labeling for nasal decongestant and analgesic-antipyretic ingredients. However, the agency recognized that the warnings for nasal decongestants proposed in § 341.80(c)(1)(i)(*b*) and (c)(1)(ii)(*b*) of the tentative final monograph would be inconsistent with the presence of the analgesic-antipyretic ingredient(s) in the product. Therefore, to eliminate this inconsistency, the agency proposed the following warning for such products labeled for use by adults in the cough-cold combinations tentative final monograph: "Do not take this product for more than 10 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor." For products labeled for use by children 2 to under 12 years of age, the proposed warning reads as follows: "Do not give this product to children for more than 5 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor." (See 53 FR 30522 at 30563.) The agency will address this warning in the final monograph for OTC cough-cold combination drug products, in a future issue of the Federal Register.

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22. One comment contended that the agency's proposed drug interaction precautions for adults and children in § 341.80(c)(1)(i)(*d*) and § 341.80(c)(1)(ii)(*d*), respectively, essentially duplicate statements required in other warnings. The comment requested that the proposed warning in § 341.80(c)(1)(i)(*c*) be modified to include the "Drug Interaction Precaution" information in § 341.80(c)(1)(i)(*d*) to read as follows: "Do not take this product if you are being treated for heart disease, depression, high blood pressure, thyroid disease, diabetes, or have difficulty in urination due to enlargement of the prostate gland unless directed by a doctor." Likewise, the comment requested that the proposed warning in § 341.80(c)(1)(ii)(*c*) be modified to include the "Drug Interaction Precaution" information in § 341.80(c)(1)(ii)(*d*) to read: "Do not give this product to children who are being treated for heart disease, thyroid disease, diabetes, high blood pressure, or depression unless directed by a doctor." The comment concluded that these revisions would eliminate redundancy in the warnings language.

The agency agrees that the statements are similar but does not agree that drug interaction precautions should be combined with warnings. The agency believes the drug interaction precaution needs to be highlighted in order to adequately inform individuals who may not otherwise be aware of serious (even life-threatening) adverse effects due to potentiation of the adverse effects of one drug by another taken concurrently.

In discussing drug interactions, the Cough-Cold Panel stated that it had recommended appropriate labeling for drug interactions where there are serious concerns (41 FR 38312 at 38335). In the case of nasal decongestants, the Cough-Cold Panel stated that patients taking other drugs (e.g., monoamine oxidase inhibitors whose action can intensify sympathomimetic drug action), should not use oral nasal decongestants except under the advice and supervision of a physician (41 FR 38312 at 38397). The Cough-Cold Panel therefore recommended a specific warning, in the form of a drug interaction precaution, to alert the subgroup of the OTC nasal decongestant target population taking prescription medication for certain

chronic disease conditions, to their special risk in using OTC nasal decongestants concurrently. The Cough-Cold Panel recommended the following drug interaction precaution statement: "Do not take this product if you are presently taking a prescription antihypertensive or antidepressant drug containing a monoamine oxidase inhibitor except under the advice and supervision of a physician." (See 41 FR 38312 at 38423.) For these reasons, the agency also proposed this drug interaction warning for OTC sympathomimetic amine bronchodilator drugs (41 FR 38312 at 38370 through 38373).

The agency discussed this statement in the tentative final monograph for OTC nasal decongestant drug products (50 FR 2220, January 15, 1985). In response to the Cough-Cold Panel's recommendation, two comments contended that terms such as "antihypertensive," "antidepressant," and "monoamine oxidase inhibitor" (MAOI) are highly technical; that only a small percentage of the population is likely to understand this warning; and that including such a warning in the labeling of an OTC drug is contrary to the well-established principle that unnecessary or confusing precautions tend to dilute the significance of all instructions in the labeling and, hence, should be avoided (50 FR 2220 at 2231). Accordingly, the agency proposed to simplify the precaution statement as follows: "*Drug interaction precaution.* Do not take this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor." (See proposed § 341.80(c)(1)(i)(*d*).) Also with the tentative final monograph, the agency proposed to add new § 341.80(c)(1)(ii)(*d*) for children, as follows: "*Drug Interaction Precaution:* Do not give this product to a child who is taking a prescription drug for high blood pressure or depression, without first consulting the child's doctor." The wording for OTC bronchodilator drug products was similarly revised in the tentative final monograph (47 FR 47520 at 47523) and the final monograph (51 FR 35326 at 35338).

After publication of the tentative final monograph for OTC nasal decongestant drug products, the agency became aware of a need to modify the wording of the drug interaction precaution statement. Information was submitted to the agency showing that the antitussive ingredient dextromethorphan interacts with prescription drugs containing MAOI's. Case reports and articles in the literature describe severe reactions, including death, from this combination of drugs. In preparing a proposal to amend the final monograph for OTC antitussive drug products to provide for a new drug interaction precaution for that class of OTC drugs, the agency determined a need to modify the language of the existing precaution statement for OTC bronchodilator and nasal decongestant drugs, largely because of expanded use of MAOI drugs. There is evidence that MAOI drugs are also being used to treat conditions, such as bulimia and panic disorder, that are not readily associated with depression. Further, the newer MAO B inhibitors are being used to treat Parkinson's disease. Finally, the use of MAOI's in hypertension has essentially ceased. In order to have consistent language among the three drug classes, the agency published proposals to amend the antitussive final monograph (57 FR 27666), bronchodilator final monograph (57 FR 27662), and the nasal decongestant tentative final monograph (57 FR 27658) to provide for the following warning:

Drug interaction precaution. Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult your doctor before taking this product.

The case reports and literature articles are discussed in detail in the proposed amendment to the final monograph for OTC antitussive drug products (57 FR 27666).

The comments received in response to the proposed amendments are discussed in detail in a final rule for OTC antitussive drug products (58 FR 54232, October 20, 1993) and OTC bronchodilator drug products (58 FR 54238, October 20, 1993). In brief, four comments that suggested modifications to the wording of the drug interaction precaution statement were not adopted, and one comment that suggested a 2-week washout period be included was adopted.

Accordingly, the agency is amending § 341.80(c)(1)(i)(*d*) for OTC nasal decongestant drug products to read:

Drug interaction precaution. Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Also, the agency is amending § 341.80(c)(1)(ii)(*d*) to read:

Drug interaction precaution. Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

23. Three comments contended that the agency should not require the warning for topical nasal decongestants proposed in § 341.80(c)(2)(iii)(*b*) of the tentative final monograph, which reads: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

One comment contended that the warning should not be required because systemic distribution of topical nasal decongestants is minimal. A second comment stated that such a warning is not warranted for topical products containing oxymetazoline. Referring to studies in dogs that compared the doses of oxymetazoline given intranasally and intravenously to elicit a cardiovascular effect (i.e., increase in blood pressure) and that showed substantial differences, the comment indicated that the amount of oxymetazoline required to elicit any systemic effect by the intranasal route would be virtually unachievable with marketed products. Based on the amount of the drug which is required to cause a systemic effect, the comment argued that there is no reason to believe that patients with cardiac problems, diabetes, or hyperthyroidism would be at any greater risk than the general population. In addition, the comment stated that its review of adverse experience files showed no cardiovascular side effect from oxymetazoline that was not associated with significant overuse, either in frequency of use, quantity of use, or both. The comment stated that the agency's proposed warning not to overuse the product deals adequately with risks to patients with cardiac problems, diabetes, or hyperthyroidism and that the additional warning is unnecessary.

The third comment indicated that the proposed warning should be deleted from the monograph because it is conjectural that systemic effects can occur as a result of absorption from the gastrointestinal tract if an excessive amount of topically applied nasal decongestant drug is swallowed. The comment stated that it was unaware of any data that support the position that an excessive amount of drug can be, or

is, swallowed when the product is used as directed. The comment cited numerous studies to support its position (Refs. 1 through 19). In addition, the comment attached a summary of published studies addressing the issue of intranasally-applied decongestants and possible cardiovascular changes (Ref. 20). The summary indicated that oral threshold doses reported to be associated with changes in pulse rate and/or blood pressure are 6 to 10 times higher than the maximal dose of phenylephrine or ephedrine administered intranasally. In the case of phenylephrine hydrochloride, the comment stated that if an entire dose of a 0.5-percent nasal spray, which contains 1.5 mg phenylephrine hydrochloride, were ingested, it would amount to only a small fraction of the Category I recommended oral dose of 10 mg for this drug. In the case of 0.5 percent ephedrine sulfate, a typical adult dose of 0.6 mg would be delivered and, 100 percent of the dose, if ingested, would amount to only a small fraction of the Cough-Cold Panel's recommended oral dose of 8 to 12 mg as a bronchodilator (41 FR 38312 at 38408).

The agency has reviewed the studies cited by one comment as well as other pertinent information concerning the side effects caused by topical nasal decongestants. Based on its review of the available data and information, the agency concludes that the warning—concerning the use of topical nasal decongestants in patients with heart disease, high blood pressure, thyroid disease, and diabetes—as discussed in the tentative final monograph (50 FR 2220 at 2222 to 2223) is appropriate for topical nasal decongestant drug products containing ephedrine or one of its salts, phenylephrine hydrochloride, naphazoline hydrochloride, oxymetazoline hydrochloride, and xylometazoline hydrochloride. The agency does not believe that the studies adequately support the safe use of topical nasal decongestants in patients with heart disease, high blood pressure, thyroid disease, or diabetes without the supervision of a physician. Further, the agency's adverse reaction data indicate that, after rebound congestion, cardiovascular effects are among the most numerous adverse effects reported.

The agency has reviewed its adverse reaction report files (Ref. 21) and finds that cardiovascular effects such as bradycardia, tachycardia, hypertension, and hypotension have been reported for products containing topical nasal decongestants, particularly for oxymetazoline. In most of the cases of cardiovascular effects, the topical nasal decongestant drug was reported to be the only drug used by the patient and was believed to be the suspect drug. Based on these adverse reaction files, the agency is concerned that certain individuals may be more susceptible to developing cardiovascular effects when using topical nasal decongestants. Further, although topical nasal decongestant drugs are recommended for no more than 3 days use, the agency is aware that excessive use of topical nasal decongestants does occur (see comment 2 in section I.A. of this document). Such excessive use could also increase the possibility that individuals with the conditions listed in the warning might develop adverse effects.

The agency does not believe that the studies submitted by one of the comments adequately support the safe use of topical nasal decongestants containing ephedrine or one of its salts, phenylephrine hydrochloride, naphazoline hydrochloride, oxymetazoline hydrochloride, or xylometazoline hydrochloride in patients with heart disease, high blood pressure, thyroid disease, or diabetes without the supervision of a physician. A number of the studies (Refs. 1 through 8) were not useful to evaluate topical effects of the nasal decongestants because the drugs were administered by oral or injectable routes. In 11 of the submitted studies (Refs. 9 through 19), nasal decongestants were administered intranasally in subjects with cardiovascular disorders, diabetes, or thyroid disease. In 1 of the 11 studies (Ref. 19), the number of hypertensive subjects could not be determined. In the remaining 10 studies, 833 subjects were studied but only 50 subjects had the conditions referred to in the warning. Thus, the agency does not consider this limited number of subjects adequate to support deletion of the warning.

The data also show that the oral doses of some topical nasal decongestants that are required to produce adverse reactions exceed the recommended topical dosages; however, none of the submitted data address the extent of absorption of nasal decongestants from the nasal mucosa, and this may be more analogous to intravenous administration than to oral administration of the drug. Many drugs (e.g., sublingual nitroglycerin, nitroglycerin spray, corticosteroids) are absorbed well from the mucosa of the oropharynx and can be more rapidly and completely absorbed than when ingested orally.

Further, the submitted data do not contain sufficient information to exclude the systemic effects alluded to in the warning. Actual data on blood pressure changes were not provided in most of the studies, and the degree of absorption of the drugs from topical intranasal administration was not addressed. Although topical nasal decongestants are administered in smaller doses than the oral doses of these drugs, the safety of these drugs when used without physician supervision by patients with heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland has not been adequately demonstrated.

Based on the above reasons, the agency is retaining the following warning for topical nasal decongestant products containing ephedrine, phenylephrine hydrochloride, naphazoline hydrochloride, oxymetazoline hydrochloride, or xylometazoline hydrochloride that was proposed in the tentative final monograph: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

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(13) Slodki, S.J., and C.A. Montgomery, "Clinical Comparison of Oxymetazoline and Ephedrine in Nasal Decongestion," *Current Therapeutic Research*, 7(1):19–22, 1965.

(14) Cohen, B.M., and E.P. Duffy, "Physiologic and Clinical Estimates of the Relief of Nasal Flow Obstruction in Allergic Rhinitis: Effects of a Topical Decongestant (Oxymetazoline)," *Journal of Asthma Research*, 7(2):65–73, 1969.

(15) Bumbalo, T.S., "Xylometazoline HCl—a New Nasal Medication for Pediatric Use (an Evaluation)," *Western Medicine*, 1:9–19, 1946.

(16) Kolodny, A.L., "Ba–11391 (Otrivin), a New Imidazoline Vasoconstrictor with Lessened Side Effects," *Antibiotic Medicine and Clinical Therapy*, 6(8):152–457, 1959.

(17) Biesalski, P., and K. Marquart, "Therapeutic Aspects of Rhinitis in Early Childhood, Thermoelectrode Investigations with Nasal Decongestants ("Zur Behandlungder Rhinitis im fruhen Kindesalter. Thermoelektrische Untersuchungen an abschwellenden Nasenmittein")," (English Translation), *Schweizerische Medizinische Wochenschrift*, 89(19):510–512, 1959.

(18) Jacques, A.A., and V.H. Fuchs, "A New Topical Nasal Decongestant," *The Journal of the Louisiana State Medical Society*, 111:384–386, 1959.

(19) Hagen, W.J., and M.G. Trelles, "A New Local Decongestant of Unusually Low Toxicity," *The Eye, Ear, Nose, and Throat Monthly*, 39:56–57, 1960.

(20) "Summary of Published Evidence Relating to the Issue of Intranasally-Applied Decongestants and Possible Cardiovascular Changes," The Proprietary Association, Washington, Appendix A of Comment No. C206, Docket No. 76N–052N, Dockets Management Branch.

(21) Department of Health and Human Services, Food and Drug Administration, "Spontaneous Reporting System, Line Listing of Adverse Reports: Nasal–76–93," 1976–1993, in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

24. One comment contended that the proposed warnings in § 341.80 for topical nasal decongestant sprays and drops (which state: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor;" "Do not exceed recommended dosage because burning, stinging, sneezing, or increase of nasal discharge may occur;" and "Do not use this product for more than 3 days. If symptoms persist, consult a doctor.") do not apply to its company's "innovative and unique one-way metered pump spray delivery system." The comment explained that the metered delivery system for its topical nasal decongestant drug products substantially reduces dosage variability, assures uniform dosage and spray pattern, and thereby further minimizes any possibility of significant systemic absorption and systemic side effects. For this reason, the comment recommended that for these products the agency eliminate the warning in proposed § 341.80(c)(2)(iii)(*b*) not to use topical nasal decongestants if certain disease conditions are present. Stating that the spray pattern achieved with the pump virtually eliminates the nasal irritation and rebound congestion sometimes associated with conventional sprays and drops and that marketing experience has confirmed the purpose of the pump's design, the comment also contended that the warnings proposed in § 341.80(c)(2)(i)(*a*) and (c)(2)(iii)(*a*) concerning burning, stinging, etc., and a restriction to only 3 days' dosage should not be required for its metered pump products.

The comment did not submit any data to support its contention that the use of a metered pump delivery system makes the above mentioned warnings unnecessary. Furthermore, the agency believes that regardless of the uniformity of the dosage and spray pattern of a topical nasal decongestant, the pharmacologic action of nasal decongestant active ingredients can produce adverse reactions in some susceptible individuals who have heart disease, high blood pressure, diabetes, etc. Thus, in the interest of consumer safety, the warning proposed in § 341.80(c)(2)(iii)(*b*) would still be applicable, regardless of the nasal spray delivery system. Also, a uniform dosage and spray pattern would not eliminate the possibility of overuse of the topical nasal decongestant drug product. An individual might use too much of the spray by repeatedly applying the medication or by using the product longer than the recommended 3 days use. Thus, rebound congestion could occur and the warning in § 341.80(c)(2)(iii)(*a*) would be applicable. The agency is unaware of data to support the comment's contention that a uniform dosage and spray pattern could help to lessen adverse effects such as burning, stinging, sneezing, etc., which might be caused by an excessive dose of a topical nasal decongestant. In the absence of data, the agency cannot agree with the comment that the warning regarding burning, stinging, sneezing in § 341.80(c)(2)(i)(*a*) (redesignated as § 341.80(c)(2)(i)(B) in this final monograph) is unnecessary for its pump spray delivery system. Therefore, the agency concludes that the warnings for topical nasal decongestants mentioned by the comment are applicable regardless of the spray delivery system.

The agency notes that a request of the type submitted by the comment (for deletion of certain warnings for a specific metered pump delivery system) could be considered as a request for an exemption from the monograph requirements or as a request for a monograph deviation. For an exemption, which would require the submission of a petition to amend the final monograph, data would have to be submitted to support the comment's contention that certain warnings are unnecessary for the metered pump spray delivery system. An exemption from these warning statements could then be included in the monograph for all nasal decongestant ingredients marketed in the specified metered dose spray dosage form along with the specifications for the specific metered pump spray delivery system. The agency believes that it would be difficult to write such specifications for inclusion in a monograph and thus considers a monograph deviation to be a more suitable alternative. A monograph deviation is covered by the regulations in 21 CFR 330.11. These regulations provide for the submission of a limited new drug application (NDA) covering only the deviation from the final monograph. Under these regulations, data submitted in support of an NDA for a product that deviates from an OTC drug final monograph must be in the form required by 21 CFR 314.50. Also, the request must include a statement that the product meets all conditions of the applicable OTC drug monograph except for the deviation for which approval is requested. The application may omit all information except that pertinent to the deviation. For the particular product discussed in the comment, the manufacturer should provide sufficient manufacturing control data to assure FDA of the uniformity of the metered dose delivery and of the spray pattern claimed for the drug product, and should include adequate clinical data to confirm that the warnings are unnecessary.

25. One comment recommended that the following statements be allowed for topical nasal decongestants marketed in a one-way metered pump delivery system: "Won't draw back nasal fluids," "unique one-way pump prevents draw-back contamination," "protects against

draw-back contamination," and "unique metered spray delivers a controlled/metered dose." In addition, the comment contended that "accurate" statements such as "long lasting relief" are appropriate for oxymetazoline-containing nasal decongestant drug products.

The agency believes that information describing a metered dose delivery system, such as that recommended by the comment, is product specific and above and beyond the scope of the standards set by this final monograph for OTC nasal decongestant drug products.

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. Two principal conditions determined during the review are allowable ingredients and the allowable labeling for those ingredients. The FDA has determined that it is not practical—in terms of time, resources, and other considerations—to set standards for all labeling found in OTC drug products. Accordingly, OTC drug monographs regulate only labeling related in a significant way to the safe and effective use of drug products by consumers. OTC drug monographs establish the allowable labeling for the following: the product statement of identity; the names of active ingredients; the indications for use; the directions for use; the warnings against unsafe use, side effects, and adverse reactions; and the claims concerning the mechanism of drug action. Accordingly, such information as that recommended by the comment is outside the scope of the OTC drug review.

The agency emphasizes that even though such information is outside the scope of the OTC drug review, it may be used in labeling subject to the prohibitions in section 502 of the act relating to labeling that is false or misleading. Such information will be evaluated by the agency on a case by case basis in conjunction with normal enforcement activities relating to that section of the act. Moreover, any information that is outside the scope of the review, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information.

Regarding the comment's claim of "long lasting relief" for oxymetazoline-containing nasal decongestant drug products, the agency notes that oxymetazoline hydrochloride has a frequency of use of "not more often than every 10 to 12 hours" which is the longest duration of action of any topical nasal decongestant in the monograph. As stated in the tentative final monograph for OTC nasal decongestant drug products, the "duration of effect has been included in the established dosages and directions for these products by stating the frequency of use (in terms of hours), which indirectly tells the consumer the duration of the products' effects" (50 FR 2220 at 2236). Although not included in the monograph, the agency has no objection to a statement such as "long lasting relief" appearing in the labeling of an OTC nasal decongestant drug product containing oxymetazoline hydrochloride. However, as stated above, such statements are subject to the prohibitions in section 502 of the act and may not appear in any portion of the labeling required by the monograph and may not detract from such required information.

26. Two comments suggested that the proposed warning for oral nasal decongestants in § 341.80(c)(1)(i)(*a*) and (c)(1)(ii)(*a*) (which states: "Do not exceed recommended dosage because at higher doses nervousness, dizziness, or sleeplessness may occur.") be revised. One comment suggested revising the warning sections to state: "Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician." This comment stated that, as the warning presently reads, it might suggest to consumers that nervousness, dizziness, and sleeplessness are the only consequences of exceeding the recommended dose, which is not necessarily so. The comment added that "nervousness, dizziness, and sleeplessness are significant enough to be a separate warning as they may, on occasion, occur at the recommended dose." The second comment suggested that the warning sections be rewritten to state: "Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, consult a doctor." The comment explained that a patient's medical history information is needed before a doctor can appropriately advise the patient whether to continue the same dose, decrease the dose, or discontinue the drug if the above-mentioned symptoms occur.

The agency agrees with the comments that the warnings for oral nasal decongestants proposed in § 341.80(c)(1)(i)(*a*) and (c)(1)(ii)(*a*) of the tentative final monograph could be revised to make them separate statements. Both comments proposed the same first statement, which is the same language as proposed in the tentative final monograph and which the agency is adopting in this final monograph. However, the comments differ in their suggested second statement. The second comment did not state to discontinue use of the drug if the above-mentioned symptoms occur. The agency believes that if nervousness, dizziness, or sleeplessness occur with use of a nasal decongestant drug, it is best to advise the consumer to discontinue use of the drug as a safety measure, and to consult a doctor for advice. In addition, in order to emphasize that the drug should not be overused, the agency is requiring that the first part of the warning appear on the label of the product in boldface type. Therefore, in the final monograph, the warnings read as follows: "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

27. One comment contended that the proposed warning for topical nasal decongestants in § 341.80(c)(2)(i)(*a*) (which states: "Do not exceed recommended dosage because burning, stinging, sneezing, or increase of nasal discharge may occur.") does not appear to be justified on the basis of consumer information and should be deleted from the monograph. The comment stated that one major firm reviewed its consumer complaint file on nasal sprays over a period of 5 years and found an average complaint rate of less than one complaint per million packages sold. The comment added that other firms have reported similar data. The comment questioned the logic of the cause and effect statement contained in the warning as it applies to topical nasal decongestant sprays and drops, i.e., that the reactions of "burning, stinging, sneezing, or increase of nasal discharge" will be the result of exceeding the recommended dosage. The comment argued that even if an excessive amount of spray or drops is used, which seems highly unlikely, the solution will either run out of the nose or drain to the back of the throat or both. In either case, the comment indicated that the amount of liquid that will adhere to the nasal mucosa is relatively constant.

In the tentative final monograph for OTC nasal decongestant drug products, the agency reviewed a related comment regarding the warning "Do not exceed recommended dosage because burning, stinging, sneezing, or increase of nasal discharge may occur." The agency concluded that this warning statement should apply to all topical nasal decongestant active ingredients administered as a drop, spray, jelly, or in an inhalant dosage form. (See 50 FR 2220 at 2232 to 2233.)

The agency also reviewed the labeling of topical nasal decongestant drug products previously approved under NDA's. The NDA labeling for products containing the nasal decongestant active ingredient oxymetazoline contained the statement: "Local stinging and slight burning can occur with any topical nasal decongestant" (Ref. 1). The NDA labeling for a product containing xylometazoline hydrochloride contained the following statement in the "Adverse Reactions" section: "Because of the pharmacological relationship among sympathomimetic nasal decongestants, the following types of effects may occur: burning, stinging, dryness of the nasal mucosa, sneezing; * * *." (Ref. 2). Furthermore, the AMA "Drug Evaluations Annual" describes typical adverse reactions of topical nasal decongestants as temporary discomfort such as stinging, burning, or dryness of the nasal mucosa, while the specific adverse reactions for naphazoline, oxymetazoline, and xylometazoline include sneezing as well (Ref. 3). Thus, the agency concludes that a warning concerning burning, stinging, sneezing, or an increase in nasal discharge is supported by clinical evidence and that the consumer complaint data, as presented by the comment, are inadequate to substantiate deletion of such a warning from the monograph. Based on the NDA labeling and AMA "Drug Evaluations," the agency believes that burning, stinging, sneezing, or an increase in nasal discharge may occur at recommended dosages and has revised the warning into two separate warnings to clarify that these side effects can occur at recommended doses. Therefore, the following revised warnings are being included in the final monograph: "Do not exceed recommended dosage," and "This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge." Additionally, in order to emphasize that the drug should not be overused, the agency is requiring that the warning "Do not exceed recommended dosage" appear on the label of the product in boldface type.

References

(1) Copy of FDA approved labeling from NDA 14–717, in OTC Vol. 04NFM, Docket No. 76N–052N, Dockets Management Branch.

(2) Copy of FDA approved labeling from NDA 11–919 in OTC Vol. 04NTFM, Docket No. 76N–052N, Dockets Management Branch.

(3) "Drug Evaluations Annual," American Medical Association, Milwaukee, WI, p. 408 and pp. 415–418, 1991.

28. One comment disagreed with the agency's proposed warning for topical nasal decongestant drug products containing 1 percent phenylephrine hydrochloride, which states: "Frequent use of this product may cause nasal congestion to recur or worsen." The comment contended that the data in the two clinical studies (comparing the safety and effectiveness of phenylephrine 1 percent vs. phenylephrine 0.5 percent) that were reviewed by the agency in the tentative final monograph (50 FR 2220 at 2229) were insufficient to warrant the proposed warning. The comment argued that the agency itself admits that "* * * the differences in side effects between the two groups [0.5 percent vs. 1 percent phenylephrine] were not statistically significant" (50 FR 2229). The comment stated that one of the studies, by Jolly et al. (Ref. 1), confirms this view by noting that "The higher incidence of responses which probably reflects rebound hyperemia in the 1-percent group (19 percent) as compared to the 0.5-percent group (4 percent) is of questionable significance from the statistical standpoint." The comment added that Jolly et al. question the reliability of the method used in the study for assessing side effects. In addition, the comment contended that even if one were to assume that the method of data collection on side effects used by Jolly et al. was unquestionable, the two studies are not confirmatory in relation to the "possible" effect seen in the Jolly et al. study. The comment also mentioned that critical information (i.e., the use of prestudy medication and the baseline conditions of individuals who were reported to have experienced the side effect of congestion during drug usage periods) is missing from the assessment of side effects in these studies.

In summary, the comment stated that the two clinical studies were designed to assess efficacy, and the methodology was not sufficiently sensitive to define confidently a comparative safety profile for the two concentrations (0.5 and 1 percent) of phenylephrine. The comment concluded that because the suggestive data form at best a possible link of a side effect and are insufficient to warrant a label warning for products containing 1 percent phenylephrine, the proposed warning should not be included in the final monograph.

The agency disagrees with the comment that the two clinical studies were designed to assess only effectiveness. Information in the manufacturer's comment shows that the two clinical studies were conducted to assess "* * * the relative safety of the two concentrations," and "* * * to compare the tolerance exhibited * * * to [0.5 and 1 percent phenylephrine hydrochloride nose drops) under conditions of exaggerated (i.e., maximum limit of the present recommended dosage) use" (Ref. 2). In reviewing the Jolly et al. study (Ref. 1), the agency observed that:

> Twelve subjects who received the 1-percent concentration and 10 who received the 0.5-percent concentration experienced side effects such as headache, nausea, dizziness, nasal edema, and erythema. The differences in side effects between the two groups were not statistically significant. However, FDA notes that the data did suggest that the 1-percent concentration seemed more likely to induce rebound congestion. The investigator also noted that the 0.5-percent concentration may be slightly better tolerated (Ref. 3).

As discussed by the Cough-Cold Panel in its report, topical nasal decongestants are known to cause rebound congestion with continued frequent use (41 FR 38312 at 38396 to 38403). However, the Cough-Cold Panel felt that the problem could be minimized if topical nasal decongestants are administered in accordance with label directions at recommended intervals for periods not exceeding 3 days (41 FR 38396). Rebound congestion occurs when topical nasal decongestants (i.e., nasal sprays, drops, jellies, and some inhalants) are used too often and for too long a period of time. Prolonged and continued use of topical nasal decongestants causes the nasal mucous membranes to become more congested and swollen as the effect of the drug wears off. The recurrence of congestion causes the user to reapply the drug. Repeated applications of the drug cause the nasal passages to reopen, but only briefly. This effect leads to continued use of the drug and perpetuates the rebound phenomenon. As discussed in comment 2, the agency has concluded that the 3-day use warning does not adequately explain to consumers the problem of rebound congestion. Therefore, the agency is clarifying the 3-day use warning as follows: "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor." These same revisions are being made in the 7-day use warning for l-desoxyephedrine that appears in § 341.80(c)(2)(ii) of this final monograph.

Based on the above discussion, the agency is deleting the specific warning for 1 percent phenylephrine hydrochloride that was proposed in the tentative final monograph in § 341.80(c)(2)(v) and is instead requiring that 1 percent phenylephrine hydrochloride, as well as all other

topical nasal decongestants except l-desoxyephedrine, bear the warning "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor." This warning appears in §§ 341.80 (c)(2)(iii)(A), (c)(2)(v), (c)(2)(viii), and (c)(2)(ix) of this final monograph.

The agency's detailed comments and evaluations of the data are on file in the Dockets Management Branch (Ref. 3).

References

(1) Jolly, E. R. et al., "Comparative Determination of Two Formulations of Neosynephrine," draft of unpublished study, Comment No. C0125, Docket No. 76N–0052, Dockets Management Branch.

(2) Comment No. C0125, Docket No. 76N–0052, Dockets Management Branch.

(3) Letter from W. E. Gilbertson, FDA, to E. J. Hiross, Sterling Drug, Inc., coded LET081, Docket No. 76N–052N, Dockets Management Branch.

29. One comment stated that, to its knowledge, no studies exist which show a definite association between the use of propylhexedrine and the occurrence of rebound congestion. The comment stated that one 2-week study and a single-dose study cited by the Cough-Cold Panel show that rebound congestion is not a problem with propylhexedrine, and a third study was ambiguous and results only "suggest a possible rebound congestion" (41 FR 38312 at 38402). The comment added that there are no studies which conclude that 3 days is the duration of therapy which reduces any risk of rebound congestion, and contended that the agency's proposed 3-day use limitation warning in § 341.80(c)(2)(vi) and (c)(2)(x) is arbitrary and unsubstantiated. The comment recommended that the agency revise proposed § 341.80(c)(2)(vi) and (c)(2)(x) to read: "Not to be used for prolonged periods."

The agency has reevaluated the studies cited by the comment (Refs. 1, 2, and 3). One study by Connell (Ref. 1) involved 64 adults with nasal congestion associated with acute coryza. The study was designed to compare the effect of a propylhexedrine inhaler on nasal airway resistance measured before inhalation to develop baseline data and after inhalation to measure the response pattern. With respect to this study, the Cough-Cold Panel stated that "measurements made 4 hours after the initial inhalation, that is, 2 hours after the repeat inhalation, suggest a possible rebound congestion" (41 FR 38312 at 38402). In a single-dose study by Hamilton (Ref. 2), the nasal decongestant effect of a propylhexedrine inhaler was compared with a placebo inhaler in 50 adult subjects with nasal congestion due to head cold. The subjects were divided equally between active and placebo groups. This study concluded that drug action of the propylhexedrine inhaler compared to placebo was demonstrated and that there were no suggestions of adverse effects. The Cough-Cold Panel had reviewed this study and stated that "no side effects or evidence of rebound congestion was noted" (41 FR 38312 at 38402). Another study by Connell (Ref. 3), which was not discussed by the Cough-Cold Panel, consisted of a comparison between groups of normal volunteers assigned to active and placebo inhalers (20 active and 10 placebo). Subjects were instructed to use a dose of two inhalations per nostril every 4 hours during the waking hours for a 2-week period. The study concluded that there were no signs of "rebound congestion" in the 20 normal volunteers who used the propylhexedrine inhaler every 4 hours for 2 weeks.

The agency agrees with the Cough-Cold Panel that the first study by Connell (Ref. 1) does suggest rebound congestion. In addition, although no rebound was seen with the single-dose study performed by Hamilton (Ref. 2), this is not sufficient proof that rebound does not occur because rebound is more likely to occur with repeated doses. The second study by Connell (Ref. 3) was intended to measure rebound after use of the propylhexedrine inhaler. Although the study concluded that there were no signs of rebound in 20 normal volunteers, the agency believes it would have been more meaningful if the study had included a number of subjects with nasal congestion associated with head colds or acute coryza as well as some subjects who used the recommended dose of two inhalations every 2 hours for a number of days. Thus, the agency believes that the second Connell study (Ref. 3) does not establish that rebound congestion due to propylhexedrine inhalation under actual use conditions does not occur.

Other references indicate that sympathomimetic amines can cause rebound congestion (Refs. 4 and 5). For example, one source notes that side effects of propylhexedrine include rebound congestion, headache, and, in rare instances, an increase in blood pressure (Ref. 4). Another source states that a major limitation of therapy with nasal decongestants is that loss in efficacy and "rebound" hyperemia and worsening of symptoms often occur with chronic use or when the drug is stopped (Ref. 5).

Regarding the comment's contention that the 3-day use limitation warning is arbitrary and unsubstantiated, the agency concluded in the tentative final monograph that the 3-day warning is justified in view of the Cough-Cold Panel's finding "that nasal decongestants can produce rebound congestion after a short period of use," i.e., 4 to 6 hours; as well as by prolonged use caused by habitual use for varying periods of time (50 FR 2232). Moreover, the agency finds the comment's suggested warning "Not to be used for prolonged periods" to be too vague and indefinite. Because some individuals have a tendency to use topical nasal decongestants for prolonged periods, the agency believes that it is important to specifically state how long the product should be used. Because rebound congestion can occur after a short period of use, the agency believes that a 3-day use limitation provides a reasonable period of time for relief of nasal congestion as well as an adequate margin of safety against the development of rebound congestion. Thus, the comment's recommendation is not being accepted.

The agency has determined that it is important to inform consumers of the consequences of too frequent or prolonged use of propylhexedrine or other topical nasal decongestants. Such products will have to bear the following warning: "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor." (See also comment 2 in section I.A. of this document and comment 28 in section I.E. of this document.)

References

(1) Connell, J., "Analysis of Study Designed to Characterize 'Benzedrex' Inhaler Response with Nasal Airway Resistance Measurements and Nasal Congestion Ratings," draft of unpublished study, in OTC Vol. 040253.

(2) Hamilton, L., "Analysis of Study Designed to Characterize Propylhexedrine Inhaler Activity as Measured by Nasal Airway Resistance and Nasal Congestion Criteria," draft of unpublished study, in OTC Vol. 040272.

(3) Connell, J., "Analysis of Nasal Airflow Study Designed for the Determination of 'Rebound Congestion' from the 'Benzedrex' Inhaler," draft of unpublished study, in OTC Vol. 040272.

(4) Harvey, S. C., "Sympathomimetic Drugs," in "Remington's Pharmaceutical Sciences," 18th ed., edited by A. R. Gennaro et al., Mack Printing Co., Easton, PA, p. 884, 1990.

(5) Hoffman, B. B., and R. J. Lefkowitz, "Catecholamines and the Sympathomimetic Drugs," in "The Pharmacological Basis of

Therapeutics," 8th ed., edited by A. G. Gilman et al., Pergamon Press, Inc., New York, p. 216, 1990.

II. Summary of Significant Changes From the Proposed Rule

1. In order to allow for flexibility in the labeling of products, the agency has revised the indications in § 341.80(b)(1) to allow manufacturers to choose from among any of the indications (i.e., the common cold (cold), allergic rhinitis, or sinusitis) for nasal decongestant drug products that are consistent with the intended use of the product. (See comment 14 in section I.E. of this document)

2. The agency is not including proposed § 341.80(b)(2), "Other allowable indications" in this final monograph, but is revising and incorporating the statements proposed in that section of the tentative final monograph into the indications included in § 341.80(b)(2) of this final monograph. (See comments 13 and 16 in section I.E. of this document.)

3. Because the phrases "For the temporary relief of" and "Temporarily relieves" are interchangeable, the option of using either phrase is included in § 341.80(b) of the final monograph. (See comment 15 in section I.E. of this document.)

4. The agency is including the term "sinus congestion" in the indications in § 341.80(b)(2)(iv) and (v), and the word "temporarily" has also been added so that the phrase reads: "* * * temporarily relieves sinus congestion and pressure." (See comments 16 and 17 in section I.E. of this document.)

5. In order to conform to numbering specified in 1 CFR 21.11(h), the numbering of many of the warnings proposed in § 341.80(c) has been changed. Specifically, paragraphs (*a*) through (*d*) have been designated as (A) through (D) in this final monograph. Likewise, in the directions proposed in § 341.80(d), paragraphs (*a*) and (*b*) have been designated as (A) and (B).

6. The agency has revised the warning for oral nasal decongestants in proposed § 341.80(c)(1)(i)(*a*) and (c)(1)(ii)(*a*) (designated as § 341.80(c)(1)(i)(A) and (c)(1)(ii)(A) in this final monograph) to provide the information in two separate statements. The agency is also requiring that the first part of the warning appears on the label of the product in boldface type so that the warnings now read as follows: "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor." (See comment 26 in section I.E. of this document.)

7. The agency has revised the warning for oral nasal decongestants in proposed § 341.80(c)(1)(i)(*b*) and (c)(1)(ii)(*b*) (designated as § 341.80(c)(1)(i)(B) and (c)(1)(ii)(B) in this final monograph) to delete the language that restricted use of the product to only 7 days. The revised warning reads as follows: "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor." (See comment 21 in section I.E. of this document.)

8. To be consistent with the wording of other warnings for children, the agency has revised the warning proposed in § 341.80(c)(1)(ii)(*c*) (designated as § 341.80(c)(1)(ii)(C) in this final monograph), "Do not give this product to children who have heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor," as follows: "Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor." Likewise, the warning proposed in § 341.80(c)(2)(ix)(*b*) (designated as § 341.80(c)(2)(viii)(B) in this final monograph), "Do not use this product in children who have heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor," has been revised as follows: "Do not use this product in a child who has heart disease * * *."

9. The agency has divided the warning for topical nasal decongestants proposed in § 341.80(c)(2)(i)(A) into two separate warnings and is requiring that the first warning appear on the label of the product in boldface type as follows: "Do not exceed recommended dosage." [sentence in boldface type] and "This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge." These two warnings are being included in the final monograph in § 341.80(c)(2)(i)(A) and (c)(2)(i)(B), respectively. Inclusion of these two warnings has necessitated a change of proposed § 341.80(c)(2)(i)(*b*) to § 341.80(c)(2)(i)(C). (See comment 27 in section I.E. of this document.)

10. To inform and warn consumers about the possibility of the occurrence of rebound congestion with prolonged and excessive use of topical nasal decongestants, the agency has expanded the warning in proposed § 341.80(c)(2)(iii)(*a*), § 341.80(c)(2)(vi), § 341.80(c)(2)(ix), and § 341.80(c)(2)(x) (designated as § 341.80(c)(2)(iii)(A), § 341.80(c)(2)(v), § 341.80(c)(2)(viii), and § 341.80(c)(2)(ix), respectively, in this final monograph) as follows: "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor." (See comment 2 in section I.A. of this document.)

11. The agency is deleting the warning proposed for 1 percent phenylephrine hydrochloride in § 341.80(c)(2)(v) and is instead requiring that 1 percent phenylephrine bear the warning for all topical nasal decongestants in § 341.80(c)(2)(iii)(A). (See comment 2 in section I.A. of this document and comment 28 in section I.E. of this document.)

12. To be consistent with the drug interaction precaution statement used for OTC antitussive and bronchodilator drug products, the agency has revised § 341.80(c)(1)(i)(*d*) (now designated as § 341.80(c)(1)(i)(D)) to read:

Drug interaction precaution. Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

The drug interaction precaution statement in § 341.80(c)(1)(ii)(*d*) (now designated as § 341.80(c)(1)(ii)(D)) is similarly revised to read:

Drug interaction precaution. Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

(See comment 22 in section I.E. of this document.)

13. The agency is adding § 341.80(d)(2)(iv)(A)(*2*) for 0.025-percent aqueous oxymetazoline hydrochloride solution to provide for use by children 2 to under 6 years of age, and removing § 341.90(m). (See comment 8 in section I.C. of this document.)

14. The agency is revising § 341.80(d)(2)(vii)(A)(*2*) for 0.05-percent aqueous xylometazoline hydrochloride solution to provide for use by children 2 to under 6 years of age. The agency also is not including proposed § 341.90(n) in this final monograph. (See comment 8 in section I.C. of this document.)

15. The agency is adding the statement "Use only recommended amount." to the directions for oxymetazoline hydrochloride (§ 341.80(d)(2)(iv)(A)(*2*)), xylometazoline hydrochloride (§ 341.80(d)(2)(vii)(A)(*2*)), and

phenylephrine hydrochloride (§ 341.80(d)(2)(v)(A)(4)) products labeled for use by children 2 to under 6 years of age. The agency is also requiring that such products have either a calibrated dropper or a metered-dose spray that delivers no more than a stated amount of drug per three drops or three sprays. (See comment 8 in section I.C. of this document.)

16. The agency has revised the directions statements, where appropriate, as follows: "Adults and children 12 years of age and over,". The agency has added the phrase "* * * and children 12 years of age and over" to the directions to clarify that the 12 years and over age group should receive an adult dose.

17. The agency is not including proposed § 341.80(e) (which states: "The word 'physician' may be substituted for the word 'doctor' in any of the labeling statements above.") in this final monograph because the agency has amended § 330.1 (21 CFR 330.1) to permit the interchangeability of certain terms, including "physician" and "doctor," in all OTC drug monographs. (See 59 FR 3998, January 28, 1994.)

18. The agency is revising the paragraph designations in § 341.3 *Definitions* in that § 341.3((e) and (f) are being changed to § 345.3(f) and (g), respectively) and is adding new § 341.3(h) for *Calibrated dropper*. (See comment 8 in section I.C. of this document.)

19. The agency has determined that for an active ingredient to be included in an OTC drug final monograph, it is necessary to have publicly available chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products. Because l-desoxyephedrine and racephedrine hydrochloride are not currently standardized and characterized for quality and purity in official compendia, i.e., the United States Pharmacopeia (U.S.P.), they are not included in this final monograph. However, should interested parties develop appropriate standards that are included in the U.S.P., this final monograph will be amended to include one or both of these ingredients. In the interim, the final monograph will be reserved for entries for l-desoxyephedrine and racephedrine hydrochloride as topical nasal decongestants. These ingredients are being included in § 310.545(a)(6)(ii)(B), nonmonograph ingredients, until appropriate compendial standards are developed.

III. The Agency's Final Conclusions on OTC Nasal Decongestant Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective and not misbranded. Specifically, the following ingredients are included in this final monograph as OTC oral nasal decongestants: Phenylephrine hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate. The following ingredients are included as topical nasal decongestants: Ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, propylhexedrine, and xylometazoline hydrochloride. The status of phenylpropanolamine preparations as an oral nasal decongestant is deferred at this time. All other ingredients for OTC nasal decongestant use in this rulemaking are considered nonmonograph ingredients: Beechwood creosote (topical), bornyl acetate (topical), camphor (topical), cedar leaf oil (topical), l-desoxyephedrine (topical), ephedrine (oral), ephedrine hydrochloride (oral), ephedrine sulfate (oral), racephedrine hydrochloride (oral/topical), eucalyptol/eucalyptus oil (topical), menthol/peppermint oil (topical), allyl isothiocyanate (mustard oil) (topical), thenyldiamine hydrochloride (topical), thymol (topical), and turpentine oil (spirits of turpentine) (topical). The agency has established 21 CFR 310.545 in which it lists certain active ingredients that are not generally recognized as safe and effective for certain OTC drug uses. The following ingredients are presently listed in 21 CFR 310.545(a)(6)(ii) for nasal decongestant drug products: Allyl isothiocyanate, camphor (lozenge), beechwood creosote (oral), eucalyptol (lozenge), eucalyptol (mouthwash), eucalyptus oil (lozenge), eucalyptus oil (mouthwash), menthol (mouthwash), peppermint oil (mouthwash), thenyldiamine hydrochloride, thymol, thymol (lozenge), thymol (mouthwash), and turpentine oil. In this final rule, the agency is amending 21 CFR 310.545(a)(6)(ii) by adding the following nasal decongestant ingredients: Beechwood creosote (topical), bornyl acetate (topical), cedar leaf oil (topical), l-desoxyephedrine (topical), ephedrine (oral), ephedrine hydrochloride (oral), ephedrine sulfate (oral), and racephedrine hydrochloride (oral/topical). These ingredients appear in new § 310.545(a)(6)(ii)(B), while previous § 310.545(a)(6)(ii) is redesignated § 310.545(a)(6)(ii)(A). Any drug product marketed for use as an OTC nasal decongestant that is not in conformance with the monograph (21 CFR part 341, subparts A, B, and C) is considered a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) and misbranded under section 502 of the act and cannot be marketed for this use unless it is the subject of an approved application. An appropriate citizen petition to amend the monograph may also be submitted under 21 CFR 10.30.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (50 FR 2220 at 2238). FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule will require some relabeling for products containing monograph ingredients. Manufacturers will have 1 year to implement this relabeling. This final rule will also require reformulation of any products containing beechwood creosote (topical), bornyl acetate (topical), cedar leaf oil (topical), l-desoxyephedrine (topical), ephedrine sulfate (oral), and racephedrine hydrochloride (oral/topical). For all other nonmonograph ingredients listed above, the effective date was May 7, 1991. The impact to the final rule appears to be minimal. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the regulatory flexibility Act, no further analysis is required.

The agency is removing existing warning and caution statements in § 369.20 for "NASAL PREPARATIONS: OIL BASE," "NASAL PREPARATIONS

IN PLASTIC SPRAY CONTAINERS," "NASAL PREPARATIONS: VASOCONSTRICTORS (AMPHETAMINE, EPHEDRINE, EPINEPHRINE, METHAMPHETAMINE, AND OTHERS OF SIMILAR ACTIVITY)," "PHENYLEPHRINE HYDROCHLORIDE PREPARATIONS, ORAL" and the terms "PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE" and "AND OTHERS OF SIMILAR ACTIVITY" in the entry "NASAL PREPARATIONS: VASOCONSTRICTORS (PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE, PHENYLPROPANOLAMINE, AND OTHERS OF SIMILAR ACTIVITY)" because these portions of the regulations are superseded by the requirements of the nasal decongestant final monograph (21 CFR part 341).

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 341

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310, 341, and 369 are amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by redesignating the text of paragraph (a)(6)(ii) as paragraph (a)(6)(ii)(A), by adding new (a)(6)(ii)(A) heading and paragraphs (a)(6)(ii)(B) and (d)(23), and by revising paragraph (d) introductory text and paragraph (d)(1) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(6) * * *

(ii) *Nasal decongestant drug products*—(A) *Approved as of May 7, 1991.* * * *

(B) *Approved as of August 23, 1995.*

Bornyl acetate (topical)
Cedar leaf oil (topical)
Creosote, beechwood (topical)
l-desoxyephedrine (topical)
Ephedrine (oral)
Ephedrine hydrochloride (oral)
Ephedrine sulfate (oral)
Racephedrine hydrochloride (oral/topical)

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(23) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(9) through (a)(10)(iii), and (a)(11) through (a)(18)(i) of this section.

* * * * *

(23) August 23, 1995, for products subject to paragraph (a)(6)(ii)(B) of this section.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

4. Section 341.3 is amended by adding new paragraphs (f), (g), and (h) to read as follows:

§ 341.3 Definitions.

* * * * *

(f) *Oral nasal decongestant drug.* A drug that is taken by mouth and acts systemically to reduce nasal congestion caused by acute or chronic rhinitis.

(g) *Topical nasal decongestant drug.* A drug that when applied topically inside the nose, in the form of drops, jellies, or sprays, or when inhaled intranasally reduces nasal congestion caused by acute or chronic rhinitis.

(h) *Calibrated dropper.* A dropper calibrated such that the volume error incurred in measuring any liquid does not exceed 15 percent under normal use conditions.

5. Section 341.20 is added to subpart B to read as follows:

§ 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:

(a) *Oral nasal decongestants.* (1) Phenylephrine hydrochloride.

(2) Pseudoephedrine hydrochloride.

(3) Pseudoephedrine sulfate.

(b) *Topical nasal decongestants.* (1) [Reserved]

(2) Ephedrine.

(3) Ephedrine hydrochloride.

(4) Ephedrine sulfate.

(5) [Reserved]

(6) Naphazoline hydrochloride.

(7) Oxymetazoline hydrochloride.

(8) Phenylephrine hydrochloride.

(9) Propylhexedrine.

(10) Xylometazoline hydrochloride.

6. Section 341.80 is added to subpart C to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "nasal decongestant."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section, as appropriate, and may contain any additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion") (which may be followed by any of the following in paragraphs (b)(1) (i), (ii), and (iii) of this section):

(i) "due to" (select one of the following: "the common cold" or "a cold").

(ii) "due to" (select one of the following: "hay fever," "hay fever (allergic rhinitis)," "hay fever or other upper respiratory allergies," or "hay fever or other upper respiratory allergies (allergic rhinitis)").

(iii) "associated with sinusitis."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) (Select one of the following: "For the temporary relief of" or "Temporarily relieves") (select one of the following: "stuffy nose," "stopped up nose," "nasal stuffiness," or "clogged up nose.")

(ii) (Select one of the following: "Reduces swelling of," "Decongests," or "Helps clear") "nasal passages; shrinks swollen membranes."

(iii) "Temporarily restores freer breathing through the nose."

(iv) "Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure."

(v) "Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *Oral nasal decongestants*—(i) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in § 341.20 (a)(1), (a)(2), and (a)(3) when labeled for adults.* (A) "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(D) "*Drug interaction precaution.* Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

(ii) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in § 341.20 (a)(1), (a)(2), and (a)(3) when labeled for children under 12 years of age.* (A) "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(D) "*Drug interaction precaution.* Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product."

(iii) *For oral nasal decongestant products labeled for both adults and children under 12 years of age.* The labeling of the product contains the warnings identified in paragraph (c)(1)(i) of this section.

(2) *Topical nasal decongestants*—(i) *For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for adults.* (A) "Do not exceed recommended dosage." [sentence in boldface type]

(B) "This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge."

(C) "The use of this container by more than one person may spread infection."

(ii) [Reserved]

(iii) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20 (b)(2), (b)(3), (b)(4), (b)(6), (b)(7), (b)(8), and (b)(10) when used as nasal sprays, drops, or jellies and when labeled for adults.* (A) "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(B) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(iv) *For products containing naphazoline hydrochloride identified in § 341.20(b)(6) at a concentration of 0.05 percent.* "Do not use this product in children under 12 years of age because it may cause sedation if swallowed."

(v) *For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for adults.* "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(vi) *For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for children under 12 years of age.* The labeling of the product contains the warnings identified in paragraph (c)(2)(i) of this section.

(vii) [Reserved]

(viii) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (b)(3), (b)(4), (b)(6), (b)(7), (b)(8), and (b)(10) when used as nasal sprays, drops, or jellies and when labeled for children under 12 years of age.* (A) "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(B) "Do not use this product in a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(ix) *For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for children under 12 years of age.* "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(x) *For topical nasal decongestant products labeled for both adults and for children under 12 years of age.* The labeling of the product contains the applicable warnings identified in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), and (c)(2)(v) of this section.

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *Oral nasal decongestants*—(i) *For products containing phenylephrine hydrochloride identified in § 341.20(a)(1).* Adults and children 12 years of age and over: 10 milligrams every 4 hours not to exceed 60 milligrams in 24 hours. Children 6 to under 12 years of age: 5 milligrams every 4 hours not to exceed 30 milligrams in 24 hours. Children 2 to under 6 years of age: 2.5 milligrams every 4 hours not to exceed 15 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(ii) *For products containing pseudoephedrine hydrochloride or*

pseudoephedrine sulfate identified in § 341.20 (a)(2) and (a)(3). Adults and children 12 years of age and over: 60 milligrams every 4 to 6 hours not to exceed 240 milligrams in 24 hours. Children 6 to under 12 years of age: 30 milligrams every 4 to 6 hours not to exceed 120 milligrams in 24 hours. Children 2 to under 6 years of age: 15 milligrams every 4 to 6 hours not to exceed 60 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(2) *Topical nasal decongestants*—(i) [Reserved]

(ii) *For products containing ephedrine, ephedrine hydrochloride, or ephedrine sulfate identified in § 341.20(b) (2), (3), and (4)*—(A) *Nasal drops or sprays—For a 0.5-percent aqueous solution.* Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(B) *Nasal jelly—For a 0.5-percent water-based jelly.* Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours.

(iii) *For products containing naphazoline hydrochloride identified in § 341.20(b)(6)*—(A) *Nasal drops or sprays*—(*1*) *For a 0.05-percent aqueous solution.* Adults and children 12 years of age and over: 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*2*) *For a 0.025-percent aqueous solution.* Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(B) *Nasal jelly*—(*1*) *For a 0.05-percent water-based jelly.* Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*2*) *For a 0.025-percent water-based jelly.* Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(iv) *For products containing oxymetazoline hydrochloride identified in § 341.20(b)(7)*—(A) *Nasal drops or sprays*—(*1*) *For a 0.05-percent aqueous solution.* Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(*2*) *A 0.025-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.027 milligrams of oxymetazoline per three drops or three sprays.* Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly—For a 0.05-percent water-based jelly.* Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(v) *For products containing phenylephrine hydrochloride identified in § 341.20(b)(8)*—(A) *Nasal drops or sprays*—(*1*) *For a 1-percent aqueous solution.* Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*2*) *For a 0.5-percent aqueous solution.* Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*3*) *For a 0.25-percent aqueous solution.* Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(*4*) *A 0.125-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.135 milligrams of phenylephrine per three drops or three sprays.* Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Use only recommended amount. [previous sentence in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly*—(*1*) *For a 1-percent water-based jelly.* Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*2*) *For a 0.5-percent water-based jelly.* Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*3*) *For a 0.25-percent water-based jelly.* Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(vi) *For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form.* The product delivers in each 800 milliliters of air 0.40 to 0.50 milligrams of propylhexedrine. Adults and children 6 to under 12 years of age (with adult supervision): 2 inhalations in each nostril not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(vii) *For products containing xylometazoline hydrochloride identified in § 341.20(b)(10)*—(A) *Nasal drops or sprays*—(*1*) *For a 0.1-percent aqueous solution.* Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(*2*) *A 0.05-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.054 milligrams of xylometazoline per three drops or three sprays.* Children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Use only recommended amount. Do not exceed 3 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly*—(*1*) *For a 0.1-percent water-based jelly.* Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) *For a 0.05-percent water-based jelly.* Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 8 to 10 hours. Children under 6 years of age: consult a doctor.

(viii) *Other required statements—For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form.* (A) "This inhaler is effective for a minimum of 3 months after first use."

(B) "Keep inhaler tightly closed."

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

7. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.20 [Amended]

8. Section 369.20 *Drugs; recommended warning and caution statements* is amended by removing the entries for "NASAL PREPARATIONS: OIL BASE," "NASAL PREPARATIONS IN PLASTIC SPRAY CONTAINERS," "NASAL PREPARATIONS: VASOCONSTRICTORS (AMPHETAMINE, EPHEDRINE, EPINEPHRINE, METHAMPHETAMINE, AND OTHERS OF SIMILAR ACTIVITY)," "PHENYLEPHRINE HYDROCHLORIDE PREPARATIONS, ORAL," and the terms "PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE" and "AND OTHERS OF SIMILAR ACTIVITY" in the entry "NASAL PREPARATIONS: VASOCONSTRICTORS (PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE, PHENYLPROPANOLAMINE, AND OTHERS OF SIMILAR ACTIVITY)."

Dated: August 4, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–20456 Filed 8–22–94; 8:45 am]

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federal register

Tuesday
August 23, 1994

Part III

Department of the Interior

Bureau of Indian Affairs
25 CFR Parts 200 and 216

Office of Surface Mining Reclamation and Enforcement
30 CFR Part 710, et al.

Surface Coal Mining and Reclamation Operations; Initial Regulatory Program for Indian Lands; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 200 and 216

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 710, 715, 716, 717, and 750

RIN 1029–AB65

Surface Coal Mining and Reclamation Operations; Initial Regulatory Program for Indian Lands

AGENCIES: Bureau of Indian Affairs and Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) and the Office of Surface Mining Reclamation and Enforcement (OSM) are amending their regulations to remove the current initial program for Indian lands and revise the existing initial program for non-Indian lands to apply to Indian lands. These amendments enable operators on Indian lands initial program sites, in appropriate circumstances, to reclaim to the latest technical and environmental standards of the permanent program, eliminate inconsistencies between the Indian and non-Indian lands initial programs, ensure equal treatment of operators on Indian and non-Indian lands, and clarify regulatory and compliance ambiguities. This rule also amends the permanent program for Indian lands to reflect the foregoing amendments and revises related information collection provisions.

EFFECTIVE DATE: September 22, 1994.

FOR FURTHER INFORMATION CONTACT: Billie E. Clark, Jr., Branch of Federal and Indian Programs, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Brooks Towers, 1020 15th Street, Denver, CO 80202; Telephone: 303–844–2829.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Proposed Rule

On March 22, 1993, the Bureau of Indian Affairs (BIA) and the Office of Surface Mining Reclamation and Enforcement (OSM) of the U.S. Department of the Interior published in the **Federal Register** at 58 FR 15404 a proposed rule to remove the Indian lands initial program at 25 CFR Part 216, Subpart B, and amend the non-Indian lands initial program at 30 CFR Chapter VII, Subchapter B, to cover Indian lands. OSM also proposed to make conforming revisions in the Indian lands permanent program and to revise related information collection provisions.

In the notice, OSM and BIA stated that the proposed rule would, among other things:

(1) Require operators on initial program Indian lands to adhere to the initial program performance standards at 30 CFR Chapter VII, Subchapter B;

(2) Allow such operators to avail themselves of 30 CFR 710.11(e), under which they could choose to meet either the initial program performance standards at 30 CFR Chapter VII, Subchapter B, or counterpart permanent program performance standards at 30 CFR Chapter VII, Subchapter K;

(3) Thereby allow such operators to reclaim to the latest technical and environmental standards of the permanent program; and

(4) Eliminate inconsistencies between the Indian and non-Indian lands initial programs, ensure equal treatment of surface coal mine operators on Indian and non-Indian lands, and clarify regulatory and compliance ambiguities.

The proposed rule provided a public comment period and offered to hold a public hearing. The public comment period closed on April 21, 1993. Two requests for a public hearing were received but later withdrawn, and no hearing was held.

B. History of Affected Provisions

The Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), Pub. L. 95–87, as amended, 30 U.S.C. §§ 1201–1328, provides for initial and permanent programs for the regulation by the Secretary of the Interior (the Secretary) of surface coal mining and reclamation operations on Indian lands. The Indian lands initial program is codified in the Federal regulations at 25 CFR Part 216, Subpart B (42 FR 63395, December 16, 1977 and 47 FR 13326, March 30, 1982). The Indian lands permanent program is codified at 30 CFR Part 750 (49 FR 38462, September 28, 1984). SMCRA also provides for initial and permanent programs for the regulation of surface coal mining and reclamation operations on non-Indian lands. The initial program for non-Indian lands is codified in the Federal regulations at 30 CFR Chapter VII, Subchapter B (42 FR 62639, December 13, 1977). Permanent program performance standards for non-Indian lands are codified at 30 CFR Chapter VII, Subchapter K.

As first promulgated, the performance standards of the Indian lands initial program at 25 CFR Part 216, Subpart B, were nearly identical to those of the non-Indian lands initial program at 30 CFR Parts 715 and 716. However, there were differences. The most important difference was that the Indian lands initial program included provisions at 25 CFR 216.112 through 216.114 for tribal involvement in inspection, enforcement, and civil penalty proceedings. Also, the Indian lands initial program did not include provisions, as found in the non-Indian lands initial program at 30 CFR 715.19, governing the use of explosives. Furthermore, except for the provisions governing steep-slope mining at 25 CFR 216.111, the Indian lands initial program did not include special performance standards comparable to those for non-Indian lands at 30 CFR Part 716.

On September 28, 1984 (49 FR 38462), OSM published a rule that, among other things, amended the Indian lands initial program to remove the tribal involvement provisions at 25 CFR 216.112 through 216.114. In the preamble to that rule, OSM stated that those provisions were superseded by the permanent program provisions at 30 CFR Parts 842, 843, and 845. Specific provisions to protect Indian interests were also included in 30 CFR Part 750. See e.g. 30 CFR 750.18. OSM determined that having one set of uniform rules made administration of the Act simpler and more efficient and that the change would cause no undue hardship on non-complying operators (49 FR 38464, September 28, 1984). Hence, the major reason for having separate Indian and non-Indian lands initial programs was eliminated.

On February 14, 1991 (56 FR 6224), OSM amended the non-Indian lands initial program to add a new provision—namely, 30 CFR 710.11(e)—that allows operators on non-Indian lands to meet any counterpart permanent program performance standard at 30 CFR Chapter VII, Subchapter K, in lieu of the initial program performance standard at 30 CFR Chapter VII, Subchapter B. Changes to the Indian lands initial program were deemed to be outside the scope of that rulemaking (56 FR 6224, 6226, February 14, 1991). Thus, while operators of non-Indian lands had the option to meet counterpart permanent program standards in lieu of initial program standards, operators on Indian lands did not have that option.

Although 30 CFR 710.11(e) did not apply to initial program Indian lands, the basis and purpose for the

promulgation of that provision are applicable to Indian lands. In explaining that new provision (56 FR 6224, February 14, 1991), OSM stated:

The Permanent Program rules [require] the latest technical and environmental standards for interpretation of the Act and are the result of more than ten years of experience in implementing the Act. They include many program revisions mandated by courts. However, in cases where the Initial Program performance standards continue to apply, Regulatory Authorities must require operators to comply with all of the earlier standards, even when compliance with Permanent Program standards would ensure implementation of [the Act] or would result in reclamation superior to that which would be achieved under the Initial Program standards.

OSM then described five examples of initial program performance standards that were outdated or for which compliance was impractical. Most of those examples are equally germane to Indian lands.

The Indian lands initial program applies to any person who conducts surface coal mining and reclamation operations on Indian lands on or after December 16, 1977. Although the Indian lands permanent program has been in effect since September 28, 1984, operators on all initial program sites must continue to comply with the Indian lands initial program performance standards, even though compliance with counterpart permanent program performance standards would ensure implementation of the Act and could result in superior reclamation. At the present time, there is only one interim program mine in operation on Indian lands. Interim program sites include sites at which surface coal mining operations were complete prior to June 28, 1985 (eight months following the effective date of the Indian lands permanent program) and to surface coal mining operations operating under an interim authorization pending issuance of a permanent program permit (See 30 CFR 750.11(c)). This rulemaking affects only such sites.

II. Discussion of Final Rule

This rule moves the Indian lands initial program regulations at 25 CFR Part 216.100(b), into a new section, but would not change its substance. Part 216, Subpart B would be deleted as proposed. The rule also amends the permanent program for Indian lands at 30 CFR 750.16 to reflect the foregoing changes. The rule also amends the information collection statements at 30 CFR 716.10, 717.10, and 750.10.

These amendments, among other things, allow operators on Indian lands initial program sites to avail themselves of the provisions of 30 CFR 710.11(e), under which operators may choose to meet either the initial program performance standards at 30 CFR Chapter VII, Subchapter B, or counterpart permanent program performance standards at 30 CFR Chapter VII, Subchapter K.

Removal of 25 CFR Part 216, Subpart B

25 CFR section 216.100(b) provides that the requirements of 25 CFR part 216, Subpart B shall be incorporated in all existing and new contracts entered into for coal mining on Indian lands. Although OSM proposed to delete 25 CFR Part 216, Subpart B, OSM has decided to retain the contents of section 216.100(b) by redesignating the section as section 200.12 *Contract Term Incorporation*, and making a technical revision to reflect the fact that the requirements of Subpart B have been replaced by 30 CFR Part 750. This change reflects the fact that the requirement of 25 CFR section 216.100(b) would not be addressed by the amendments to 30 CFR Chapter VII. Accordingly, the existing requirement of 25 CFR section 216.100(b) is being redesignated without substantive change.

As discussed above, prior to this rule 25 CFR Part 216, Subpart B, comprised the Indian lands initial program. Although 25 CFR Part 216, Subpart B, appears in the BIA regulations at 25 CFR Chapter I, the OSM Director is responsible for administering the Indian lands initial program under the general guidance of the Assistant Secretary for Land and Minerals Management.

The performance standards of 30 CFR Chapter VII, Subchapter B, do not place any additional unreasonable burdens on operators on Indian lands initial program sites about and beyond those found in 25 CFR Part 216, Subpart B. The changes will actually give OSM and operators more flexibility while ensuring compliance with the Act.

Amendments to 30 CFR

As discussed below, the amendments to 30 CFR 710.11(b), 715.11, and 750.16 make the non-Indian lands initial program at 30 CFR Chapter VII, Subchapter B, applicable to Indian lands.

Section 710.11(b)—Applicability

The "Applicability" provisions at 30 CFR 710.11(b) are amended to make the initial program regulations at 30 CFR Chapter VII, Subchapter B, applicable to Indian lands. Specifically, it requires any person who conducts surface coal mining and reclamation operations on Indian lands on or after December 16, 1977, in accordance with 30 CFR 750.11(c), to meet the performance standards of 30 CFR Chapter VII, Subchapter B. This change would, by implication, amend any provision of 30 CFR Chapter VII, Subchapter B, containing a reference to the State as the regulatory authority, to the extent that such reference would be construed as also referring to OSM as the regulatory authority on Indian lands.

This change affects operators on Indian lands initial program sites in three principal ways:

a. Permanent Program Performance Standards in Lieu of Initial Program Performance Standards

The change to 30 CFR 710.11(b) allows operators on Indian lands initial program sites to avail themselves of the provisions of 30 CFR 710.11(e), under which they may choose to meet either the initial program performance standards at 30 CFR Chapter VII, Subchapter B, or counterpart permanent program performance standards at 30 CFR Chapter VII, Subchapter K. Prior to this rulemaking, operators on non-Indian lands were able to avail themselves of section 710.11(e) while operators on Indian lands were not. With this rulemaking, operators on Indian lands may now avail themselves of section 710.11(e). This resolves an inequity. Without the change to section 710.11(b), operators on Indian lands initial program sites could be placed at a competitive and economic disadvantage when compared with operators on non-Indian land, because of performance standards that have been determined to be unnecessary for implementation of SMCRA. Thus, the change to section 710.11(b) eliminates inconsistencies between the current Indian and non-Indian lands initial programs and ensures equal treatment of operators on Indian and non-Indian lands.

This rulemaking will have no cumulative negative environmental effect. Allowing operators to choose compliance with the permanent program performance standards will ensure compliance with the Act. The permanent program performance standards represent the latest technical and environmental standards for interpretation of the Act, and are the result of more than fifteen years of experience in implementing the Act. The permanent program performance standards also include revisions mandated by courts. Hence, the Act will be complied with and environmental

impacts will be fully analyzed and considered before final decisions are reached.

b. Frequency of Inspecting Ponds That Do Not Meet Mine Safety and Health Administration Criteria

The Indian lands initial program at 25 CFR 216.108(e) required that ponds not meeting the size or other criteria of the Mine Safety and Health Administration regulation at 30 CFR 77.216(a) be examined on a weekly basis. In comparison, the non-Indian lands initial program at 30 CFR 715.17(e)(20) allows the regulatory authority to approve a reduction in the number of examinations of these ponds to four times per year. The change to 30 CFR 710.11(b) makes 30 CFR 715.17(e)(20) applicable to Indian lands and, consequently, allows OSM, the regulatory authority for Indian lands, to approve a reduction in the number of examinations of these ponds to four times per year. This change eliminates a competitive and economic disadvantage placed on Indian land operators by reducing the cost to the operator associated with such examinations.

c. Use of Explosives

Section 710(c) of the Act does not specifically require operators on Indian lands initial program sites to comply with subsection 515(b)(15) of the Act concerning the use of explosives. Therefore, the Indian lands initial program promulgated on December 16, 1977 (42 FR 63395) did not include provisions governing the use of explosives. In comparison, section 502(c) of the Act requires operators on non-Indian lands initial program sites to comply with subsection 515(b)(15) of the Act. Consequently, the non-Indian lands initial program at 30 CFR 715.19 includes provisions governing the use of explosives.

By this rulemaking, 30 CFR 710.11(b) is modified and the provisions at 30 CFR 715.19 governing the use of explosives are made applicable to Indian lands initial program sites. Section 710(d) of the Act, however, requires surface coal mine operators on Indian lands, on which such operations are conducted on and after thirty months from August 3, 1977, to comply with all of subsection 515 of the Act, including subsection 515(b)(15). Furthermore, section 710(d) of the Act requires that after the applicable thirty month period, all of the requirements of subsection 515 of the Act must be incorporated in existing and new leases issued for coal on Indian lands. The changes to 30 CFR 710.11(b) in this rulemaking are effective after the applicable 30-month period when operators on Indian lands must comply with all of the requirements of section 515 of the Act, including those concerning explosives. Therefore, 30 CFR 715.19 is made applicable to Indian lands.

Section 715.11—General Obligations

Part 715 of 30 CFR contains general initial program performance standards and includes regulations governing restoration of disturbed areas to suitable postmining land use, backfilling and grading, off-site disposal of spoil and waste materials, topsoil handling, protection of the hydrologic system, construction, inspection, and maintenance of dams, use of explosives, and revegetation. The focus of 30 CFR Part 715 is on lands regulated by the States. The "General obligations" section of this part is modified by adding a new paragraph to clarify that the general performance standards of this part are also applicable to Indian lands. Specifically, paragraph (d) is added to 30 CFR 715.11. OSM had proposed to add a new subparagraph 30 CFR 715.11(d)(1) which specifically clarified that OSM is the regulatory authority for surface coal mining and reclamation operations conducted on Indian lands initial program sites. This has been OSM's position for a number of years (See, e.g., OSM's preambles on September 28, 1984, and May 22, 1989 (54 FR 22182).). OSM has decided not to include this provision in the final rule because it is not necessary. Although such a clarification would have been useful when this program was codified in 25 CFR, such a clarification is unnecessary once the program is codified under 30 CFR, because the provisions of 30 CFR already define "regulatory authority" and specify what entities perform that role. Thus, the decision not to adopt this provision is not intended to be a substantive change from the existing rule or from the proposed rule. The issue of who may act as the regulatory authority under SMCRA on Indian lands is currently the subject of litigation [*Hopi Indian Tribe* v. *Secretary of the Interior*, No. 89–2055–JGP (D.D.C.); *Navajo Nation* v. *Babbitt*, No. 89–2066–JGP (D.D.C.) (consolidated)]. OSM anticipates the issue will be resolved in the context of that litigation.

OSM proposed a new subparagraph 30 CFR 715.11(d)(2). This provision is being renumbered and adopted. 30 CFR 715.11(d)(1). This subparagraph establishes minimum requirements for mine maps. The maps must show as of December 16, 1977, the lands where coal had not yet been removed, and the lands and structures that had been used or disturbed by a surface coal mining operation. This provision essentially duplicates 25 CFR 216.102(b). This is necessary since the effective date of the initial program for Indian lands is December 16, 1977, as opposed to May 3, 1978, for non-Indian lands, and operators still must supply the subject mine maps to OSM.

Subpart B of 25 CFR Part 216 generally requires coordination and consultation with tribes, much the same as 30 CFR Part 715 requires coordination and consultation with States and local governments. Since Subpart B of 25 CFR Part 216 is removed under this rulemaking, OSM proposed to add a provision at 30 CFR 715.11(d)(3) that requires notification of and consultation with tribal governments to the same extent as is required for State and local governments. The provision is being renumbered and adopted as 30 CFR 715.11(d). This provision reflects the important role of tribal governments in the initial program for Indian lands.

The last sentence of 30 CFR 715.11(d)(2) requires OSM to coordinate with the BIA with respect to special requirements relating to the protection of noncoal resources and the Bureau of Land Management (BLM) with respect to the requirements relating to the development, production and recovery of mineral resources. This sentence has been added to the final rulemaking to specifically recognize the responsibilities that the BIA and the BLM have on Indian lands. It essentially establishes the same requirement for the initial program as exists in 30 CFR 750.6 for the permanent program.

Sections 716.1 Through 716.10—Special Performance Standards

30 CFR Chapter VII, Subchapter B, includes provisions governing general obligations (section 716.1), steep-slope mining (section 716.2), mountain-top removal (section 716.3), special bituminous coal mines (section 716.4), anthracite coal mines (section 716.5), coal mines in Alaska (section 716.6), prime farmland (section 716.7), and information collection (section 716.10). The only counterpart to these regulations under 25 CFR Part 216, Subpart B, was the regulations governing steep-slope mining (section 216.111), which duplicates only a portion of the regulations covering steep-slope mining at 30 CFR 716.2. Under the changes made today, the additional requirements of 30 CFR Chapter VII, Subchapter B, also govern

operations on Indian lands initial program sites, as applicable.

Section 750.16—Performance Standards

30 CFR 750.16 is modified to reflect that operators on Indian lands initial program site must comply with the provisions of 30 CFR Chapter VII, Subchapter B. This is necessary since 25 CFR Part 216, Subpart B is removed by this rulemaking.

III. Response to Comments

Comments on the proposed rule were received from four entities: two tribal governments and two members of the coal industry. The proposal to allow operators to meet counterpart permanent program performance standards in lieu of meeting initial program standards was generally supported by all of the commenters. One commenter said that it favored the proposed rule since the rule would place operators on Indian lands on the same footing as operators on non-Indian lands. However, some commenters suggested that the final rule be modified to reflect specific concerns. Responses to comments on specific issues follow.

A. Combining Initial and Permanent Program Performance Standards

As provided in 30 CFR 710.11(e), for surface coal mining and reclamation operations on Indian lands initial program sites this rule allows operators to meet either the initial or the counterpart permanent program performance standards. One commenter asked whether an operator on Indian lands initial program sites could, for a performance standard applicable to a specific activity, meet part of the initial program performance standard and, for the remainder of that standard, meet the permanent program performance standard.

For example, under this rule, Indian lands initial program operations would be subject to the initial program performance standard at 30 CFR 715.19 governing the use of explosives. The counterpart permanent program performance standard is found at 30 CFR 816.61 through 816.68. The requirements of that portion of the initial program standard at 30 CFR 715.19(c) (1) and (2) are different than the counterpart requirements at 30 CFR 816.64(c) (2) and (3) about what an operator must identify in a blasting schedule. The commenter asked whether an operator could meet the permanent program requirements for those two subsections but meet the initial program requirements for the remainder of the performance standard.

The answer is no. While 30 CFR 710.11(e) allows an operator to meet either the initial or the counterpart permanent program performance standard, the operator may not pick and choose selective portions of a comprehensive standard applicable to a particular activity. In the commenter's example, 30 CFR 715.19 contains a comprehensive performance standard governing the use of explosives. Consequently, under 30 CFR 710.11(e), an operator could choose to meet all of the initial program performance standard at section 715.19 or, in the alternative, all of the permanent program performance standard governing the use of explosives at 30 CFR 816.61 through 816.68.

The approach suggested by the commenter would be impracticable to administer and could result in incomplete compliance with the minimum requirements of both the initial and permanent program performance standards. Each operator who elects to meet a permanent program performance standard in lieu of an initial program standard, is responsible for initially determining the extent of the counterpart initial and permanent program standards. OSM will in all cases have the final say regarding the validity of that determination.

B. Effect of Rule on Previously Approved Activities

One commenter was concerned that this rule would necessitate additional review and approval of activities that previously were approved under 25 CFR Part 216, Subpart B. The commenter's concern is unfounded. This rule does not negate any previous approvals given by OSM under the initial program.

One commenter suggested that this rulemaking will lower standards on initial program sites, since some of the permanent program performance standards are less stringent than the initial program performance standards. The commenter stated that the rule change appears to be only for the convenience of the operators and that alone is not a sufficient reason to lower the standards. Recognizing that both programs meet the requirements of the Act, the commenter was also concerned that the rulemaking may result in a cumulative negative effect on tribal lands. The commenter requested that the rule be modified to require OSM to make a finding that compliance with the permanent program performance standards, as opposed to the initial program performance standards, will have no negative effect and/or will not negatively impact the overall environment.

OSM disagrees. This rulemaking is expected to have no cumulative negative effect on tribal lands, for several reasons. Allowing operators to choose compliance with the permanent program performance standards will not be a problem because such compliance would constitute full compliance with the Act. The permanent program performance standards represent the latest technical and environmental standards for interpretation of the Act, and are the result of more than fifteen years of experience in implementing the Act. The permanent program performance standards also include revisions mandated by courts. Operators opting to meet the permanent program standards would be meeting requirements that satisfy the Act. OSM's approval would be required if on an initial program site an operator wished to initiate under permanent program standards an activity that under the initial program requires regulatory authority approval, or if the operator wishes to apply permanent program standards to an activity approved under the initial program; and OSM would be required to ensure compliance with the Act and the National Environmental Policy Act of 1969 (NEPA). Hence, the Act will be complied with and environmental impacts will be fully analyzed and considered before a final decision is reached.

C. OSM Coordination With Other Agencies

One commenter opposed allowing operators the right to choose permanent program performance standards over initial program performance standards without a tribe being given the opportunity to comment on and/or oppose such action. The commenter stated that the government must support the Federal policy of self-determination for tribes. Therefore, a tribe should be consulted and informed of any and all consequences of operators choosing initial program performance standards over permanent program performance standards. The commenter also stated that the tribes were not being treated as an equal to the States. A State, as the regulatory authority under the Act, can choose not to adopt this rule change in its program but a tribe, since OSM is the regulatory authority under the Act, does not have this same option. In addition, a State could adopt a more restrictive rule that would require operators to follow notice and consultation procedures before using a permanent program performance standards on an initial program site. Hence, the commenter requested that the rule provide notice and consultation with

tribes and that the operator on Indian lands initial program sites obtain prior approval from the tribes before using a permanent program performance standard in lieu of an initial program performance standard.

OSM agrees that the tribes will not be able to act as State regulatory authorities may. This is consistent with SMCRA section 710, under which OSM is the regulatory authority for Indian lands. Under section 710, tribes are not authorized to act as the regulatory authority on Indian lands, so tribes may not take the same actions as may be taken by State regulatory authorities under State primacy.

However, OSM disagrees with the commenter's concerns about consultation with tribes. As noted above, if an operator on an Indian lands initial program site chooses to utilize a permanent program performance standard in lieu of an initial program performance standard, and prior approval is required under the initial program for the activity or the operator is proposing modification of a previously approved activity, then the operator must obtain prior approval from OSM prior to conducting such activity. Prior to OSM taking action, tribes as well as other agencies will be consulted with as provided for under this final rule at 30 CFR 715.11(d)(2). Thus, the final rule requires appropriate consultation with tribes.

One commenter suggested that 30 CFR 750.6(a)(3) be amended to give tribal authorities the option of participating in inspections conducted by OSM in order to assist the tribes in their development of regulatory expertise and to prepare the tribes to assume enforcement authority once appropriate legislation is enacted.

In response to this comment, OSM states that the development of tribal regulatory expertise is beyond the scope of this rulemaking. However, it should be noted that as a routine practice OSM invites tribal and other agency officials to accompany inspectors during all Indian mine inspections.

One commenter requested that OSM consult directly with the tribal governments instead of going through the BIA. The commenter suggested that 30 CFR 750.6(d) be modified to reflect this request. The same commenter stated that tribal governments should be consulted in the same manner as State regulatory agencies, whether or not the tribes have their own regulatory programs under SMCRA.

In response to this comment, OSM states that modifying coordination procedures for the permanent program is beyond the scope of this rulemaking. However, it should be recognized that OSM consults directly with tribal governments concerning permanent program matters as required at 30 CFR 750.6(a)(4). In order to ensure that tribal concerns are fully addressed OSM consults with tribal governments on all permitting actions.

D. Tribal and State Laws

One commenter stated that tribes may undertake their own regulatory program, independent of SMCRA. The same commenter proposed that 30 CFR 715.11(a) be amended to require compliance with tribal laws and regulations for coal mining operations on Indian lands and that the provisions of 30 CFR Part 715 that refer to State and local agencies be amended to include tribal agencies. The commenter further requested that the rules reflect that if there is a conflict between State or local laws and tribal laws, with regard to surface coal mining and reclamation operations on Indian lands, that tribal law should control.

In response to this comment, OSM notes that this rulemaking neither addresses the laws and regulatory programs that tribal governments have enacted, or may enact, nor the conflicts which may exist between tribal laws and State and local laws over the regulation of surface coal mining operations on Indian lands and would not affect the applicability of such tribal laws and regulations. Hence, the concerns raised by the commenter are beyond the scope of this rulemaking. The Tribes have raised this issue in the case of *Hopi Indian Tribe* v. *Secretary of the Interior, supra*, and it may be addressed in that proceeding.

IV. Procedural Matters

Federal Paperwork Reduction Act

This rule does not contain collections of information which require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

Executive Order 12866, Regulatory Planning and Review

This rule was not subject to Office of Management and Budget Review under Executive Order 12866.

Regulatory Flexibility Act

The U.S. Department of the Interior (DOI) certifies that this document would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This determination is based on the fact the rule would permit an operator to comply with either initial program rules or permanent program rules. All seven existing mines on Indian lands in the states of Arizona, New Mexico, and Montana would be affected.

Executive Order 12778, Civil Justice Reform

This rule has been reviewed under the applicable standards of Section 2(b)(2) of Executive Order 12778, Civil Justice Reform (56 FR 55195). In general, the requirements of Section 2(b)(2) of Executive Order 12778 are covered by the preamble discussion of this rule. Additional remarks follow concerning individual elements of the Executive Order:

A. What is the preemptive effect, if any, to be given to the regulation?

The rule will have no preemptive effect, since it merely substitutes one set of Federal standards for another set, and no State performance standards or other requirements apply.

B. What is the effect on existing Federal law or regulation, if any, including all provisions repealed or modified?

This rule modifies the implementation of SMCRA as described herein, and is not intended to modify the implementation of any other Federal statute. The preceding discussion of this rule specifies the Federal regulatory provisions that are affected by this rule.

C. Does the rule provide a clear and certain legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction?

The standards established by this rule are as clear and certain as practicable, given the complexity of the topics covered and the mandates of SMCRA. As noted above, the rule will simplify the regulatory process by establishing one set of initial program regulatory provisions for all surface coal mining operations. The rule would also allow surface coal mining operations to choose to comply with permanent program standards which are in some cases less stringent than initial program standards, where OSM has determined that less stringent permanent program standards fully ensure compliance with SMCRA.

D. What is the retroactive effective, if any, to be given to the regulation?

This rule is not intended to have retroactive effect.

E. Are administrative proceedings required before parties may file suit in court? Which proceedings apply? Is the exhaustion of administrative remedies required?

No administrative proceedings are required before parties may file suit in court challenging the provisions of this

rule under section 526(a) of SMCRA, 30 U.S.C. 1276(a).

Prior to any judicial challenge to the application of the rule, however, administrative procedures must be exhausted. Applicable administrative procedures may be found at 43 CFR Part 4.

F. Does the rule define key terms, either explicitly or by reference to other regulations or statutes that explicitly define those items?

Terms which are important to the understanding of this rule are set forth in 30 CFR 700.5, 701.5 and 750.5.

G. Does the rule address other important issues affecting clarity and general draftsmanship of regulations set forth by the Attorney General, with the concurrence of the Director of the Office of Management and Budget, that are determined to be in accordance with the purposes of the Executive Order?

The Attorney General and the Director of the Office of Management and Budget have not issued any guidance on this requirement.

National Environmental Policy Act

OSM has prepared a final environmental assessment (EA), and has made a finding that the proposed rule would not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). A finding of no significant impact (FONSI) has been approved in accordance with OSM procedures under NEPA. The EA is on file in the OSM Administrative Record at the address specified previously (see **ADDRESSES**).

Authors

The principal authors of this proposed rule are Billie E. Clark, Federal and Indian Permitting Branch, Office of Surface Mining Reclamation and Enforcement, Denver, Colorado, and John S. Retrum, Office of the Field Solicitor, U.S. Department of the Interior, Denver, Colorado. Telephone: 303–844–2829 and 303–231–5350, respectively.

List of Subjects

25 CFR Part 200

Environmental protection, Indian lands, Mineral resources, Mines.

25 CFR Part 216

Environmental protection, Indian lands, Mineral resources, Mines.

30 CFR Part 710

Law enforcement, Public health, Reporting and recordkeeping requirements, Safety, Surface mining, Underground mining.

30 CFR Part 715

Environmental protection, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 716

Special performance standards, Steep-slope mining, Mountaintop removal, Bituminous coal mines, Prime farmlands.

30 CFR Part 717

Environmental protection, Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 750

Indian lands, Intergovernmental relations, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: July 18, 1994.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

August 5, 1994.

Ada E. Deer,

Assistant Secretary, Indian Affairs.

Accordingly, 25 CFR parts 200 and 216 and 30 CFR parts 710, 715, 716, 717, and 750 are amended as set forth below:

25 CFR CHAPTER I

PART 200—TERMS AND CONDITIONS: COAL LEASES

1. The authority citation for Part 200 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*), as amended.

2. Section 200.12 is added to read as follows:

§ 200.12 Contract term incorporation.

The requirements of 30 CFR Part 750 shall be incorporated in all existing and new contracts entered into for coal mining on Indian lands.

PART 216—SURFACE EXPLORATION, MINING, AND RECLAMATION OF LANDS

3. The authority citation for Part 216 continues to read as follows:

Authority: 34 Stat. 539, 35 Stat. 312; 25 U.S.C. 355 NT; 35 Stat. 781; 25 U.S.C. 396; sec. 1, 49 Stat. 1250; 25 U.S.C. 473a; 49 Stat. 1967, 25 U.S.C. 501, 502; 52 Stat. 347, 25 U.S.C. 396 a–f; 5 U.S.C. 301.

Subpart B—[Removed]

4. Subpart B—Coal Operations, consisting of §§ 216.100–216.111, is removed in its entirety.

30 CFR CHAPTER VII

PART 710—INITIAL REGULATORY PROGRAM

5. The authority citation for Part 710 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended, and Pub. L. 100–34.

6. In § 710.11, paragraph (b) is revised to read as follows:

§ 710.11 Applicability.

* * * * *

(b) *Operations on Indian lands.* Any person who conducts surface coal mining and reclamation operations on Indian lands on or after December 16, 1977, in accordance with section 750.11(c) of this chapter, or who was otherwise subject to 25 CFR Part 216, Subpart B prior to September 22, 1994; shall comply with the performance standards of this subchapter.

* * * * *

PART 715—GENERAL PERFORMANCE STANDARDS

7. The authority citation for Part 715 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*).

8. In § 715.11, paragraph (d) is added to read as follows:

§ 715.11 General obligations.

* * * * *

(d) *Indian lands.* (1) *Mine maps.* Any person conducting surface coal mining and reclamation operations on Indian lands under this part shall submit no fewer than 7 copies of an accurate map of the mine and authorized mining areas at a scale of 1:6000 or larger. The map shall show, as of December 16, 1977, the lands where coal has not yet been removed and the lands and structures that have been used or disturbed to facilitate surface coal mining operations.

(2) *Consultation with tribal governments.* Any requirement in this part for consultation with or notification to State and local governments shall be interpreted as requiring, in like manner, consultation with or notification to tribal governments. OSM shall consult with the Bureau of Indian Affairs with respect to special requirements relating to the protection of noncoal resources and with the Bureau of Land Management with respect to the requirements relating to the development, production, and recovery of mineral resources on Indian lands.

PART 716—SPECIAL PERFORMANCE STANDARDS

9. The authority citation for Part 716 continues to read as follows:

Authority: Sections 201, 501, 527 and 529, Pub. L. 95–87, 91 Stat. 445 (30 U.S.C. 1201).

10. Section 716.10 is revised to read as follows:

§ 716.10 Information collection.

The Office of Management and Budget has determined that the information collection requirements contained in 30 CFR part 716 do not require approval under the Paperwork Reduction Act.

PART 717—UNDERGROUND MINING GENERAL PERFORMANCE STANDARDS

11. The authority citation for Part 717 continues to read as follows:

Authority: Sections 201 and 501, Pub. L. 95–87, 91 Stat. 445 (30 U.S.C. 1201).

12. Section 717.10 is revised to read as follows:

§ 717.10 Information collection.

The Office of Management and Budget has determined that the information collection requirements contained in 30 CFR part 717 do not require approval under the Paperwork Reduction Act.

PART 750—REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS ON INDIAN LANDS

13. The authority citation for Part 750 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*, as amended); and Pub. L. 100–34.

14. Section 750.10 is revised to read as follows:

§ 750.10 Information collection.

The Office of Management and Budget has determined that the information collection requirements contained in 30 CFR part 750 do not require approval under the Paperwork Reduction Act.

15. In § 750.16, the second sentence is revised to read as follows:

§ 750.16 Performance Standards.

* * * Prior to that time, the person conducting surface coal mining and reclamation operations shall adhere to the performance standards of 30 CFR Chapter VII, Subchapter B.

[FR Doc. 94–20514 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–05–M

federal register

Tuesday
August 23, 1994

Part IV

Department of the Interior

Bureau of Indian Affairs

Preservation Establishment, Additions, etc.; Seminole Indian Reservation, Florida; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proclaiming Certain Lands as Part of the Reservation of the Seminole Tribe of Indians of Florida

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary—Indian Affairs proclaimed 39.407 acres, more or less, as an addition to the reservation of the Seminole Tribe of Indians of Florida on July 1, 1994. This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.3a.

FOR FURTHER INFORMATION CONTACT: Alice A. Harwood, Bureau of Indian Affairs, Division of Real Estate Services, Chief, Branch of Technical Services, MS–4522/MIB/Code 220, 1849 C Street NW., Washington, D.C. 20240, telephone (202) 208–3604.

SUPPLEMENTARY INFORMATION: On July 1, 1994, by proclamation issued pursuant to the Act of June 28, 1934 (48 Stat. 986; 25 U.S.C. 467), the following described tracts of land, located in Hillsborough County, Florida, was added to and made a part of the Seminole Indian Reservation of Florida.

Tallahassee Meridian

Hillsborough County, Florida

All of the East ½ of the Northeast ¼ (E½NE¼) of Section 2, Township 29 South, Range 19 East, Hillsborough County, Florida, lying North of Interstate 4 and East of Orient Road, and less the part of the East ½ of the Northeast ¼ (E½NE¼) of Section 2, Township 29 South, Range 19 East, Hillsborough County, Florida, lying Northerly of State Road No. 400 and East of Orient Road, described as follows:

Commencing at the Southwest corner of the North 967.00 feet of the Northeast ¼ of the Northeast ¼ (NE¼NE¼) of said Section 2; thence run South 89°14'33" East, along the South boundary of the North 967.00 feet of said Northeast ¼ of the Northeast ¼ (NE¼NE¼), a distance of 35.47 feet to a point on the East right-of-way line of the 60.00 foot right-of-way for Orient Road for a Point of Beginning; thence continue to run South 89°14'33" East, along the South boundary of the North 967.00 feet, a distance of 526.87 feet to a point; thence run South 00°11'46" West, parallel to the West boundary of the East ½ of the Northeast ¼ (E½NE¼) of Section 2 a distance of 547.28 feet to a point of intersection with the Northerly right-of-way line of State Road No. 400; thence run South 49°12'56" West, along said right-of-way line of State Road No. 400 a distance of 633.60 feet to a point of intersection with the East right-of-way line of Orient Road; thence run the following courses along the East right-of-way line of Orient Road, North 00°00'44" West, a distance of 537.26 feet; thence South 89°59'16" West, a distance of 22.00 feet; thence North 00°00'44" West, a distance of 400.00 feet; thence South 89°59'16" West, a distance of 23.00 feet; thence North 00°00'44" West, a distance of 23.00 feet; thence North 00°00'44" West, a distance of 30.87 feet to the Point of Beginning. Containing 30.818 acres, more or less.

And

That part of the East ½ of the Northeast ¼ (E½NE¼) of Section 2, Township 29 South, Range 19 East, Hillsborough County, Florida, lying Northerly of State Road No. 400 and East of Orient Road, described as follows:

Commencing at the Southwest corner of the North 967.00 feet of the Northeast ¼ of the Northeast ¼ (NE¼NE¼) of said Section 2; thence run South 89°14'33" East, along the South boundary of the North 967.00 feet of said Northeast ¼ of the Northeast ¼ (NE¼NE¼), a distance of 35.47 feet to a point on the East right-of-way line of the 60.00 feet right-of-way for Orient Road for a point of beginning; thence continue to run South 89°14'33" East, along said South boundary of the North 967.00 feet, a distance of 526.87 feet to a point; thence run South 00°11'46" West, parallel to the West boundary of the East ½ of the Northeast ¼ (E½NE¼) of Section 2, a distance of 547.28 feet to a point of intersection with the Northerly right-of-way line of State Road No. 400; thence run South 49°12'56" West, along said right-of-way line of State Road No. 44, a distance of 633.60 feet to a point of intersection with the East right-of-way line of Orient Road; thence run the following courses along the East right-of-way line of Orient Road, North 00°00'44" West, a distance of 537.26 feet; thence South 89°59'16" West, a distance of 22.00 feet; thence North 00°00'44" West, a distance of 400.00 feet; thence South 39°59'16" West, a distance of 23.00 feet; thence North 00°00'44" West, a distance of 30.87 feet to the Point of Beginning. Containing 8.589 acres, more or less.

The above described parcels contain a total of 39.407 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

Ada E. Deer,

Assistant Secretary, Indian Affairs.

[FR Doc. 94–20679 Filed 8–22–94; 8:45 am]

BILLING CODE 4310–02–M

federal register

Tuesday
August 23, 1994

Part V

Department of Education

Office of Postsecondary Education; Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant Programs; Notice

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant Programs

AGENCY: Department of Education.

ACTION: Notice of Closing Date for Filing the Fiscal Operations Report and Application to Participate in the Federal Perkins Loan, Federal Work-Study (FWS), and Federal Supplemental Educational Opportunity Grant (FSEOG) Programs.

SUMMARY: The Secretary gives notice to institutions of higher education of the deadline for an institution to apply for fiscal year 1995 funds—for use in the 1995–96 award year—under the Federal Perkins Loan, FWS, and FSEOG programs. Under these programs, the Secretary allocates funds to institutions for students who need financial aid to meet the costs of postsecondary education. An institution is not required to establish eligibility prior to applying for funds. Institutions will be notified of the closing date for establishing institutional eligibility to participate in the Federal Perkins Loan, FWS, and FSEOG programs in the 1995–96 award year through a separate notice in the **Federal Register**.

The Secretary further gives notice that an institution that had a Federal Perkins Loan fund or expended FWS or FSEOG funds during the 1993–1994 award year is required to submit a Fiscal Operations Report to report its program expenditures as of June 30, 1994, to the Secretary.

The Federal Perkins Loan, FWS, and FSEOG programs are authorized by parts E and C, and part A, subpart 2, respectively, of title IV of the Higher Education Act of 1965, as amended.

CLOSING DATE: An institution may submit its 1993–94 Fiscal Operations Report and 1995–96 Application to Participate (FISAP) in the Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant Programs (FISAP-ED FORM 646–1; OMB No. 1840–0073) by—

(1) Submitting the completed data on a data diskette provided by the Department of Education;

(2) Creating a tape from data stored on a mainframe computer and submitting that tape in a format defined by the Department of Education; or

(3) Transmitting the data from a personal or mainframe computer through a modem.

First-time applicants will be required to submit data for the application portion of the FISAP only. Therefore, the Department is mailing only that portion of the FISAP to first-time applicants.

To ensure consideration for 1995–96 funds, an institution must submit an electronic FISAP by data diskette, tape, or modem, by October 1, 1994.

FISAPS DELIVERED BY MAIL: A diskette or tape containing FISAP data must be addressed to FISAP, c/o Universal Automation Labs (UAL), 5th Floor, 8300 Colesville Road, Silver Spring, Maryland 20910.

An institution must show proof of mailing its FISAP by October 1, 1994. Proof of mailing consists of one of the following: (1) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service, (2) a legibly dated U.S. Postal Service postmark, (3) a dated shipping label, invoice, or receipt from a commercial carrier, or (4) any other proof of mailing acceptable to the U.S. Secretary of Education.

If a FISAP is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service. An institution should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an institution should check with its local post office. An institution is encouraged to use certified or at least first-class mail.

FISAPS DELIVERED BY HAND: A diskette or tape containing FISAP data must be taken to Universal Automation Labs (UAL), 5th Floor, 8300 Colesville Road, Silver Spring, Maryland.

Hand-delivered FISAP diskettes or tapes will be accepted between 9 a.m. and 5 p.m. daily (Eastern time), except Saturdays, Sundays, and Federal holidays. Because October 1 is a Saturday this year, a FISAP that is hand-delivered will not be accepted after 5 p.m. on September 30, 1994.

FISAPS DELIVERED ELECTRONICALLY: A FISAP that is delivered electronically must be transmitted by either a personal or mainframe computer to the host ED computer using a modem. In addition, one original completed FISAP signature page and one original signed Compliance Certification form must be mailed to Electronic FISAP, c/o Universal Automation Labs (UAL), 5th Floor, 8300 Colesville Road, Silver Spring, Maryland 20910, by October 1, 1994.

FISAP INFORMATION: FISAP materials were mailed by the Department of Education in late July. An institution must prepare and submit its FISAP in accordance with the information included in the package.

The program information package is intended to aid applicants in applying for assistance under these programs. Nothing in the program information package is intended to impose any paperwork, application content, reporting, or grantee performance requirements beyond those specifically imposed under the statute and regulations governing the programs.

APPLICABLE REGULATIONS: The following regulations are applicable to these programs:

Federal Perkins Loan—34 CFR parts 674 and 668.

Federal Work-Study—34 CFR parts 675 and 668.

Federal Supplemental Educational Opportunity Grant—34 CFR parts 676 and 668.

FOR FURTHER INFORMATION CONTACT: To receive information or to request FISAP materials, contact Ms. Sandra Donelson, Fund Control Branch, Campus-Based Programs Financial Management Division, Accounting and Financial Management Service, Student Financial Assistance Programs, U.S. Department of Education, 400 Maryland Avenue, S.W., (Room 4621, ROB–3), Washington, D.C. 20202–5452. Telephone (202) 708–9751. Individuals who use a telecommunications devise for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Program Authority: 20 U.S.C. 1087aa *et. seq.*; 42 U.S.C 2751 *et seq.*; and 20 U.S.C. 1070b *et seq.*

Dated: August 17, 1994.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

(Catalog of Federal Domestic Assistance Numbers: 84.038 Federal Perkins Loan Program; 84.033 Federal Work-Study Program; and 84.007 Federal Supplemental Educational Opportunity Grant Program).

[FR Doc. 94–20632 Filed 8–22–94; 8:45 am]

BILLING CODE 4000–01–P

federal register

Tuesday
August 23, 1994

Part VI

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Advisory Committee Meeting; Recombinant DNA Research: Proposed Actions Under the Guidelines; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on September 12–13, 1994. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on September 12, 1994, at approximately 9 a.m., and will recess at approximately 6 p.m. The meeting will reconvene on September 13, 1994, at approximately 8:30 a.m. and will adjourn at approximately 5 p.m. The meeting will be open to the public to discuss Proposed Actions under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (59 FR 34496) and other matters to be considered by the Committee. The Proposed Actions to be discussed will follow this notice of meeting. Attendance by the public will be limited to space available. Members of the public wishing to speak at this meeting may be given such opportunity at the discretion of the Chair.

In accordance with the provision set forth in sec. 552b(c)(4), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on September 12 from 5 p.m., to approximately 6 p.m., for the review, discussion, and evaluation of proprietary information which is a part of a human gene therapy research proposal. The proposal and the discussion could reveal confidential trade secrets or commercial property such as patentable material.

Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, Phone (301) 496–9838, FAX (301) 496–9839, will provide materials to be discussed at this meeting, roster of committee members, and substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Wivel in advance of the meeting. A summary of the meeting will be available at a later date.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance*. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the *NIH Guidelines*. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

Dated: August 3, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94–20825 Filed 8–22–94; 8:45 am]

BILLING CODE 4141–01–M

Recombinant DNA Research: Proposed Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496).

SUMMARY: This notice sets forth proposed actions to be taken under the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee at its meeting on September 12–13, 1994. After consideration of these proposals and comments by the Recombinant DNA Advisory Committee, the Director of the National Institutes of Health will issue decisions in accordance with the NIH Guidelines.

DATES: Comments received by September 5, 1994, will be reproduced and distributed to the Recombinant DNA Advisory Committee for consideration at its September 12–13, 1994, meeting.

ADDRESSES: Written comments and recommendations should be submitted to Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities (ORDA), Building 31, Room 4B11, National Institutes of Health, Bethesda, Maryland 20892, or sent by FAX to 301–496–9839.

All comments received in timely response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Recombinant DNA Activities, Building 31, Room 4B11, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–9838.

SUPPLEMENTARY INFORMATION: The NIH will consider the following actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules:

I. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Crystal

In a letter dated July 18, 1994, Dr. Ronald Crystal of the New York Hospital-Cornell Medical Center, New York, New York, submitted a human gene transfer protocol entitled: Evaluation of Repeat Administration of a Replication Deficient, Recombinant Adenovirus Containing the Normal Cystic Fibrosis Transmembrane Conductance Regulator cDNA to the Airways of Individuals w/Cystic Fibrosis to the Recombinant DNA Advisory Committee for formal review and approval.

II. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Isner and Walsh

In a letter dated July 5, 1994, Drs. Jeffrey M. Isner and Kenneth Walsh of the St. Elizabeth's Medical Center, Tufts University, Boston, Massachusetts, submitted a human gene transfer protocol entitled: Arterial Gene Transfer for Therapeutic Angiogenesis in Patients with Peripheral Artery Disease to the Recombinant DNA Advisory Committee for formal review and approval.

III. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Gluckman

In a letter dated July 15, 1994, Dr. Jack L. Gluckman of the University of Cincinnati Medical Center, Cincinnati, Ohio, submitted a human gene transfer protocol entitled: Intratumoral Injection of Herpes Simplex Thymidine Kinase Vector Producer Cells (PA317/G1Tk1SvNa.7) and Intravenous Ganciclovir for the Treatment of Locally

Recurrent or Persistent Head and Neck Cancer to the Recombinant DNA Advisory Committee for formal review and approval.

IV. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Flotte

In a letter dated July 14, 1994, Dr. Terence R. Flotte of Johns Hopkins Children's Center, Baltimore, Maryland, submitted a human gene transfer protocol entitled: A Phase I Study of an Adeno-associated Virus-CFTR Gene vector in Adult CF Patients with Mild Lung Disease to the Recombinant DNA Advisory Committee for formal review and approval.

V. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Lyerly

In a letter received on July 18, 1994, Dr. H. Kim Lyerly of Duke University Medical Center, Durham, North Carolina, submitted a human gene transfer protocol entitled: A Pilot Study of Autologous Human Interleukin-2 Gene Modified Tumor Cells in Patients with Refractory or Recurrent Metastatic Breast Cancer to the Recombinant DNA Advisory Committee for formal review and approval.

VI. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Whitley

In a letter dated July 15, 1994, Dr. Chester B. Whitley of the University of Minnesota, Minneapolis, Minnesota, submitted a human gene transfer protocol entitled: Retroviral-Mediated Transfer of the Iduronate-2-Sulfatase Gene Into Lymphocytes for Treatment of Mild Hunter Syndrome (Mucopolysaccharidosis Type II) to the Recombinant DNA Advisory Committee for formal review and approval.

VII. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Holt and Arteaga

In a letter dated July 15, 1994, Drs. Jeffrey Holt and Carlos B. Arteaga of Vanderbilt University, Nashville, Tennessee, submitted a human gene transfer protocol entitled: Gene Therapy for the Treatment of Metastatic Breast Cancer by In Vivo Infection with Breast-Targeted Retroviral Vectors Expressing Antisense c-fos or Antisense c-myc RNA to the Recombinant DNA Advisory Committee for formal review and approval.

VIII. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Eck, Alavi

In a letter dated July 15, 1994, Drs. Stephen L. Eck and Jane B. Alavi of the University of Pennsylvania Medical Center, Philadelphia, Pennsylvania, submitted a human gene transfer protocol entitled: Treatment of Advanced CNS Malignancy w/the Recombinant Adenovirus H5.020RSVTK: A Phase I Trial to the Recombinant DNA Advisory Committee for formal review and approval.

IX. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Albelda

In a letter received on July 18, 1994, Dr. Steven M. Albelda of the University of Pennsylvania Medical Center, Philadelphia, Pennsylvania, submitted a human gene transfer protocol entitled: Treatment of Advanced Mesothelioma with the Recombinant Adenovirus H5.010RSVTK: A Phase I Trial to the Recombinant DNA Advisory Committee for formal review and approval.

X. Amendments to Sections I, III, IV, V, and Appendix M of the NIH Guidelines Regarding Consolidated Review of Human Gene Transfer Protocols

On July 18–19, 1994, the National Task Force on AIDS Drug Development held an open meeting for the purpose of identifying barriers to AIDS Drug Discovery that included a proposal to streamline the dual review process for human gene transfer experiments. Members of the Task Force recommended a consolidated review process to enhance interactions between the NIH and the FDA. As a result of the Task Force's deliberations, recommendations were adopted in order to eliminate any unnecessary overlap between the FDA and NIH review of human gene transfer proposals. Both Drs. Varmus and Kessler noted that their respective agencies would cooperate fully to effect the changes necessary to implement these recommendations. The recommendations were:

"The NIH and FDA recommend that the RAC become advisory to both the NIH Director and the FDA with regard to the review of human gene transfer protocols. In the interest of maximizing the resources of both agencies and in simplifying the method and period for review of research protocols involving human gene transfer, it is planned that the FDA and NIH institute a new consolidated review process that incorporates the following principal elements:

(1) All gene transfer protocols shall be submitted directly to the FDA. Submission will be in the format required by the FDA and the same format will be used by the RAC when public review is deemed necessary.

(2) Upon receipt, FDA review will proceed. The NIH Office of Recombinant DNA Activities (ORDA) staff will simultaneously evaluate the protocol for possible RAC review.

(3) Factors which may contribute to the need for RAC review include: (1) novel approaches, (2) new diseases, (3) unique applications of gene transfer, and (4) other issues that require further public review.

(4) Whenever possible, principal investigators will be notified within 15 working days following receipt of the submission whether RAC review will be required. (RAC reviewed applications will be forwarded to reviewers 8 weeks prior to the next quarterly RAC meeting.)

(5) Semi-annual data reporting procedures will remain the responsibility of NIH (ORDA). Semi-annual data reports will be reviewed by the RAC in a public forum."

Investigators will no longer be required to provide a separate submission to NIH/ORDA for RAC review. The FDA Division of Cellular and Gene Therapies will forward a copy of each submission to NIH/ORDA. Any protocol submitted < 8 weeks before a RAC meeting will be reviewed at the following quarterly RAC meeting.

The RAC will make recommendations regarding approval/disapproval of protocols, including any relevant stipulations, to the NIH Director. The NIH Director will transmit the RAC's recommendations/stipulations to the FDA Commissioner.

The FDA will consider such recommendations/stipulations and will be responsible for completion of review. The RAC and NIH/ORDA will no longer have the responsibility for reviewing material submitted in response to stipulation requirements or for the review of minor modifications to human gene transfer protocols.

The following proposed amendments to the NIH Guidelines reflect the new streamlined review process.

Section I (Scope of the NIH Guidelines) currently reads:

"Section I. Scope of the NIH Guidelines

"Section I–A. Purpose

"The purpose of the NIH Guidelines is to specify practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

"Section I–A–1. Any recombinant DNA experiment, which according to the NIH Guidelines requires approval by the NIH, must be submitted to the NIH or to another Federal agency that has jurisdiction for review and approval. Once approval, or other applicable clearances, has been obtained from a Federal agency other than the NIH (whether the experiment is referred to that agency by the NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval (see exception in Sections I–A–2 and I–A–3).

"Section I–A–2. Certain experiments that involve the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) shall be considered *Major Actions* (see Section IV–C–1–b–(1)), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary, to: (i) represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review (see Section III–A–2).

"Section I–A–3. Experiments involving the transfer of recombinant DNA to one or more human subjects that are not considered under Section III–A–2 may qualify for Accelerated Review (see Section III–B–2 and Appendix M–V) and will be considered as *Minor Actions* (see Section IV–C–1–b–(2)–(a)). Actions that qualify for *Accelerated Review* will be reviewed and approved by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary.

"Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see Section III–C–7)."

Section I–A is proposed to read:

"Section I. Scope of the NIH Guidelines

"Section I–A. Purpose

"The purpose of the *NIH Guidelines* is to specify practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

"Section I–A–1. If a recombinant DNA experiment requiring NIH approval is also subject to review and approval by another Federal agency, the proposed experiment must be submitted to the other Federal agency. Once approval, or other applicable clearances, has been obtained from a Federal agency other than the NIH, the experiment may proceed without the necessity for NIH review or approval, except as provided in Section I–A–1–a.

"Section I–A–1–a. Experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects shall be submitted directly to the Food and Drug Administration (FDA). Such proposals shall be submitted to the Director of the Division of Cellular and Gene Therapies, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, HFM–515, Rockville, Maryland 20852–1448, (301) 496–4709. Upon receipt, FDA will transmit all human gene transfer protocols to the NIH Office of Recombinant DNA Activities (ORDA). Simultaneously with the FDA review, NIH/ORDA will evaluate the protocol for possible RAC review. Whenever possible, Principal Investigators will be notified within 15 working days following receipt of the submission whether RAC review will be required. RAC reviewed applications will be forwarded to reviewers 8 weeks prior to the next quarterly RAC meeting. Factors that may contribute to the need for RAC review include: (i) novel approaches, (ii) new diseases, (iii) unique applications of gene transfer, and (iv) other issues that may require further public review. The RAC's recommendations, including specific requirements and stipulations, will be forwarded to the NIH Director. The NIH Director's final recommendation will be forwarded to the FDA Commissioner."

Section III (Experiments Covered by the NIH Guidelines), paragraph 1, currently reads:

"This section describes five categories of experiments involving recombinant DNA: (i) those that require RAC review and NIH and Institutional Biosafety Committee approval before initiation. . . ."

Section III, paragraph 1, is proposed to read:

"This section describes five categories of experiments involving recombinant DNA: (i) those that require Institutional Biosafety Committee approval, RAC review, and NIH Director consideration before initiation. . . ."

Section III–A currently reads:

"Section III–A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Approval Before Initiation

"Experiments in this category are considered *Major Actions* (see Section IV–C–1–b–(1)) cannot be initiated without submission of relevant information on the proposed experiment to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838, the publication of the proposal in the **Federal Register** for 15 days of comment, review by the RAC, and specific approval by the NIH (not applicable for *Expedited Review* single patient human gene transfer experiments considered under Appendix M–VI). The containment conditions for such experiments will be recommended by the RAC and set by the NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D which may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

"Section III–A–1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

"Section III–A–2. Certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) shall be considered *Major Actions* (see Section IV–C–1–b–(1) and Appendix M–III), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, to: (i) represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review. The requirement for RAC review shall not be considered to preempt any other required review or approval of experiments with one or more human subjects. Relevant Institutional Biosafety Committee and

Institutional Review Board reviews and approvals of the proposal should be completed before submission to NIH. Certain experiments involving deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects may qualify for the *Accelerated Review* process (see Section III–B–2). Certain categories of experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects and that are not covered by Section V–U, may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see Section III–C–7)."

Section III–A is proposed to read:

"Section III–A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Consideration Before Initiation (see Section IV–C–1–b–(1)).

"Section III–A–1. *Major Actions*

"Experiments described in Sections III–A–1–a and III–A–2 cannot be initiated without submission of relevant information on the proposed experiment to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892–7052, (301) 496–9838, the publication of the proposal in the **Federal Register** for 15 days of comment, review by the RAC, and specific approval by the NIH. The containment conditions for such experiments will be recommended by the RAC and, except as provided in Section III–A–2, will be set by the NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D which may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892–7052, (301) 496–9838.

"Section III–A–1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

"Section III–A–2. Major Actions Involving Human Gene Transfer Experiments

"Experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects under Section I–A–1, and that are determined appropriate for RAC review and NIH Director consideration shall be considered as a Major Action, except that the NIH Director will make a recommendation to the FDA Commissioner who will make the final decision on the proposed experiment."

Sections III–B–2 and –3 is proposed to be deleted:

"Section III–B–2. Accelerated Review of Human Gene Transfer Experiments

"As determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, certain categories of human gene transfer experiments may be considered as Minor Actions and qualify for Accelerated Review and approval (see Section IV–C–1–b–(2)–(a), Appendix M–III–A, and Appendix M–V). The RAC Chair will present a report of all NIH/ORDA approved human gene transfer protocols at the next regularly scheduled RAC meeting. If NIH/ORDA determines that an experiment does not qualify for the Accelerated Review process, the Principal Investigator must submit the proposal for full RAC review ≥ 8 weeks prior to the next scheduled RAC meeting (See Section III–A–2).

"Section III–B–3. Minor Modifications to Human Gene Transfer Experiments

"A minor modification in a human gene transfer protocol is a modification that does not significantly alter the basic design of the protocol and that does not increase risk to human subjects or the environment. After approval has been obtained by the relevant Institutional Biosafety Committee and Institutional Review Board, NIH/ORDA will consider the change in consultation with the RAC Chair and one or more RAC members, as necessary. Submit minor modifications to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The RAC Chair will provide a report on any such approvals at the next regularly scheduled RAC meeting."

Section III–C–7 (Experiments that Require Institutional Biosafety Committee Approval Before Initiation/ Human Gene Transfer Experiments Not Covered by Sections III–A–2, III–B–2, III–B–3, and Not Considered Exempt Under Section V–U) is proposed to be deleted:

"Section III–C–7. Human Gene Transfer Experiments Not Covered by Sections III–A–2, III–B–2, III–B–3, and Not Considered Exempt Under Section V–U

"Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that are not covered by Sections III–A–2, III–B–2, III–B–3, and that are not considered exempt under Section V–U must be registered with NIH/ORDA. The relevant Institutional Biosafety Committee and Institutional Review Board must review and approve all experiments in this category prior to their initiation."

Section IV–B–4–e–(5) (Roles and Responsibilities/Responsibilities of the Principal Investigator During the Conduct of Research) is proposed to be inserted:

"Section IV–B–4–e–(5). Comply with semi-annual data reporting and adverse event reporting requirements for FDA-approved human gene transfer experiments (see Appendix M–I–C)."

Section IV–C–1–b–(1) (Responsibilities of the National Institutes of Health/Specific Responsibilities) currently reads:

"Section IV–C–1–b–(1). Major Actions. To execute Major Actions, the NIH Director shall seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the Notice of Meeting and Proposed Actions to the NIH Guidelines shall be published in the **Federal Register** at least 15 days before the RAC meeting (not applicable for Expedited Review single patient human gene transfer experiments considered under Appendix M–VI). The NIH Director's decision, at his/her discretion, may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision, along with responses to public comments, shall be published in the **Federal Register**. The RAC and Institutional Biosafety Committee Chairs shall be notified of the following decisions:"

Section IV–C–1–b–(1) is proposed to read:

"Section IV–C–1–b–(1). Major Actions. To execute Major Actions, the NIH Director shall seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the Notice of Meeting and Proposed Actions shall be published in the **Federal Register** at least 15 days before the RAC meeting. The NIH Director's decision/recommendation, at his/her discretion, may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision/ recommendation, along with responses to public comments, shall be published in the **Federal Register**. The RAC and

Institutional Biosafety Committee Chairs shall be notified of the following decisions:"

Section IV–C–1–b–(1)–(d) currently reads:

"Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A;"

Section IV–C–1–b–(1)–(d) is proposed to read:

"Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A–1;"

Section IV–C–1–b–(1)–(e) is proposed to be included:

"Section IV–C–1–b–(1)–(e). Recommendations made by the NIH Director to the FDA Commissioner regarding RAC-reviewed human gene transfer experiments (see Appendix M–I–B);"

Renumber remaining sections in IV–C–1–b–(1).

Sections IV–C–1–b–(2)–a and –(b) (Responsibilities of the National Institutes of Health/Minor Actions) is proposed to be deleted:

"Section IV–C–1–b–(2)–(a). Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that qualify for the *Accelerated Review* process (see Section III–B–2);

"Section IV–C–1–b–(2)–(b). Reviewing and approving minor changes to human gene transfer protocols under Section III–A–2 and III–B–2;"

Renumber remaining sections in IV–C–1–b–(2).

Section IV–C–3 (Responsibilities of the National Institutes of Health/Office of Recombinant DNA Activities) currently reads:

"Section IV–C–3. Office of Recombinant DNA Activities (ORDA)

"ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector. ORDA shall carry out such other functions as may be delegated to it by the NIH Director, including those authorities described in Section IV–C–1–b–(2). ORDA's responsibilities include, but are not limited to the following:

"Section IV–C–3–a. Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an LD_{50} ≤100 nanograms per kilogram body weight in organisms other than *Escherichia coli* K–12 (see Section III–B–1 and Appendices F–I and F–II);

"Section IV–C–3–b. Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects, in consultation with the RAC Chair and one or more RAC members, as necessary, that qualify for the *Accelerated Review* process (see Section III–B–2);

"Section IV–C–3–c. Reviewing and approving minor changes to human gene transfer protocols approved under Sections III–A–2 and III–B–2, in consultation with the RAC Chair and one or more RAC members, as necessary;

"Section IV–C–3–d. Reviewing and approving the membership of an institution's Institutional Biosafety Committee, and where it finds the Institutional Biosafety Committee meets the requirements set forth in Section IV–B–2 will give its approval to the Institutional Biosafety Committee membership;

"Section IV–C–3–e. Publishing in the **Federal Register**:

"Section IV–C–3–e–(1). Announcements of RAC meetings and agendas at least 15 days in advance (NOTE—If the agenda for a RAC meeting is modified, ORDA shall make the revised agenda available to anyone upon request at least 72 hours in advance of the meeting);

"Section IV–C–3–e–(2). Proposed *Major Actions to the NIH Guidelines* (see Section IV–C–1–b–(1)) at least 15 days prior to the RAC meeting;

"Section IV–C–3–f. Serve as the focal point for data management of NIH-approved human gene transfer protocols approved under Sections III–A–2 and III–B–2 and registered with NIH/ORDA as required under Section III–C–7;

"Section IV–C–3–g. Serve as the executive secretary of the RAC; and

"Section IV–C–3–h. Maintain a list of *Major and Minor Actions* approved under Section III–A–2 and III–B–3 and a list of experiments registered with NIH/ORDA as described in Section III–C–7."

Section IV–C–3 is proposed to read:

"Section IV–C–3. Office of Recombinant DNA Activities (ORDA)

"ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector. ORDA shall carry out such other functions as may be delegated to it by the NIH Director. ORDA's responsibilities include, but are not limited to the following:

"Section IV–C–3–a. Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an LD_{50} ≤100 nanograms per kilogram body weight in organisms other than *Escherichia coli* K–12 (see Section III–B–1 and Appendices F–I and F–II);

"Section IV–C–3–b. Evaluating human gene transfer protocols (transmitted by the FDA) for the necessity for RAC review (see Appendix M–I–A).

"Section IV–C–3–c. Reviewing and approving the membership of an institution's Institutional Biosafety Committee, and where it finds the Institutional Biosafety Committee meets the requirements set forth in Section IV–B–2 will give its approval to the Institutional Biosafety Committee membership;

"Section IV–C–3–d. Publishing in the **Federal Register**:

"Section IV–C–3–d–(1). Announcements of RAC meetings and agendas at least 15 days in advance (NOTE—If the agenda for a RAC meeting is modified, ORDA shall make the revised agenda available to anyone upon request at least 72 hours in advance of the meeting);

"Section IV–C–3–d–(2). Proposed *Major Actions* (see Section IV–C–1–b–(1)) at least 15 days prior to the RAC meeting;

"Section IV–C–3–e. Serve as the focal point for data management of FDA-approved human gene transfer protocols (see Appendix M–I–C–2);

"Section IV–C–3–f. Serve as the executive secretary of the RAC; and

"Section IV–C–3–g. Maintain a list of *Major Actions* recommended for approval by the NIH Director to the FDA Commissioner, under Section III–A–2."

Section V–U and V–V (Footnotes and References of Sections I–IV) is proposed to be deleted:

"Section V–U. Human studies in which the induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected, are not covered under Sections III–A–2, III–B–2, or III–B–3. Such studies may be initiated without RAC review and NIH approval if approved by another Federal agency.

"Section V–V. For recombinant DNA experiments in which the intent is to

modify stably the genome of cells of one or more human subjects (see Sections III–A–2, III–B–2, and III–B–3)."

Renumber Section V–W to Section V–U.

Appendix M is revised to read as follows:

"Appendix M. Human Gene Transfer Experiments

"Appendix M–I. Human Gene Transfer Experiments—Submission Requirements

"Appendix M–I–A. Human Gene Transfer Experiments—Submission to the FDA

"In the interest of maximizing the resources of both the NIH and the FDA and in simplifying the method and period for review, research protocols involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into human subjects will be submitted directly to the FDA and considered through a consolidated review process involving both the FDA and the NIH. Submission will be in the format required by the FDA and the same format will be used by the RAC when public review is deemed necessary. Upon receipt, FDA will transmit all human gene transfer protocols to the NIH/ORDA. FDA and NIH/ORDA will simultaneously evaluate the protocol for possible RAC review. Protocols shall be submitted to the Director of the Division of Cellular and Gene Therapies, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, HFM–515, Rockville, Maryland 20852–1448, (301) 496–4709.

"Appendix M–I–B. Human Gene Transfer Experiments Requiring RAC Review and NIH Director Consideration

"Appendix M–I–B–1. Factors that may contribute to the need for RAC review include: (i) novel approaches, (ii) new diseases, (iii) unique applications of gene transfer, and (iv) other issues that require further public review. Whenever possible, Principal Investigators will be notified within 15 working days following receipt of the submission whether RAC review will be required (RAC reviewed applications will be forwarded to RAC primary reviewers 8 weeks prior to the next quarterly RAC meeting).

"Appendix M–I–B–2. Written comments submitted by the RAC primary reviewers shall be submitted to NIH/ORDA≥4 weeks before the RAC meeting at which the protocol will be reviewed.

"Appendix M–I–B–3. Written responses (including critical data in response to the primary reviewers' comments) shall be submitted by the Principal Investigator to NIH/ORDA ≥2 weeks before the RAC meeting at which the protocol will be reviewed.

"Appendix M–I–B–4. Principal Investigators will limit their oral responses to the RAC only to those questions that are raised during the meeting. Oral presentations of previously submitted material and/or critical data that was not submitted ≥2 weeks prior to the RAC meeting are prohibited.

"Appendix M–I–B–5. The RAC primary reviewers' comments should include the following:

"Appendix M–I–B–5–a. Emphasize the issues related to gene marking, gene transfer, or gene therapy.

"Appendix M–I–B–5–b. Examine the scientific rationale, scientific context (relative to other proposals reviewed by the RAC), whether preliminary in vitro or in vivo data were obtained in appropriate models and are sufficient, and whether questions related to safety, efficacy, and social/ethical considerations have been resolved.

"Appendix M–I–B–5–c. RAC primary reviews should state whether the proposal is: (i) acceptable as written, (ii) expected to be acceptable with specific revisions or after satisfactory responses to specific questions raised on review, or (iii) unacceptable in its present form.

"Appendix M–I–B–6. Following public review, the RAC's recommendations regarding the proposal will be transmitted to the NIH Director for consideration.

"Appendix M–I–B–7. The NIH Director's recommendation regarding the proposal will be transmitted to the FDA Commissioner.

"Appendix M–I–C. Human Gene Transfer Experiments—NIH and FDA Reporting Requirements

"Appendix M–I–C–1. Adverse Event Reporting

"Principal Investigators who have received approval from the FDA to initiate a human gene transfer protocol must report any serious adverse event immediately to the local Institutional Review Board, the NIH Office for Protection from Research Risks, Director of the Division of Cellular and Gene Therapies/FDA, and NIH/ORDA followed by the submission of a written report filed with each group. Reports submitted to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, 6006 Executive Boulevard, Suite 323, Bethesda, Maryland 20892–7052, (301) 496–9838.

"Appendix M–I–C–2. Semi-Annual Data Reporting

"Principal Investigators who have received approval from the FDA to initiate a human gene transfer protocol shall be required to comply with semi-annual data reporting requirements. Semi-annual Data Reporting forms will be forwarded by NIH/ORDA to the Principal Investigators. Data submitted in these reports will be evaluated by NIH/ORDA and reviewed by the RAC at its next regularly scheduled meeting."

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: August 10, 1994.

John K. Uzzell,

Acting Deputy Director for Science Policy and Technology Transfer.

[FR Doc. 94–20826 Filed 8–22–94; 8:45 am]

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Federal Register

Tuesday
August 23, 1994

Part VII

The President

Federal Register
Vol. 59, No. 162
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Presidential Documents

Title 3—

The President

Proclamation 6715 of August 18, 1994

Women's Equality Day, 1994

By the President of the United States of America

A Proclamation

Seventy-four years ago, the 19th Amendment was ratified, granting women the right to vote after many years of painstaking struggle and hard work by courageous suffragists. Empowered by the efforts of the brave and pioneering women who came before them, women today have secured positions as leaders in industry, government, and academia. They serve as role models in every aspect of our society.

The 19th Amendment did more than secure the right to vote for women. It recognized and affirmed the fundamental principle upon which this great Nation was founded—equality—"that all [persons] are created equal, that they are endowed by their Creator with certain unalienable rights, that among these are Life, Liberty and the pursuit of Happiness." The ratification of the 19th Amendment was an important step toward ensuring that the civil and political rights guaranteed by the Constitution would truly be the equal rights of all Americans.

By recognizing this previously disenfranchised segment of our society, the 19th Amendment became one of the landmark civil rights laws in America, standing side by side with the Emancipation Proclamation, and the 13th, 14th, and 15th Amendments. This year also marks the 4th anniversary of the Americans with Disabilities Act, the 30th anniversary of the Civil Rights Act of 1964, as well as the 40th anniversary of *Brown v. Board of Education*. These laws and that pivotal decision, along with the 19th Amendment, have marked the history of our Nation's progress in guaranteeing that every member of our society is treated equally under the law.

We observe "Women's Equality Day" to commemorate the ratification of the 19th Amendment almost three-quarters of a century ago. As we do so, we also honor the important contributions and achievements of women in this country, and we commit ourselves anew to fulfilling our obligation to promote equality for all Americans.

The famous woman suffragist, Helen H. Gardener, advised the Congress in calling for passage of the 19th Amendment:

> Let us either stop our pretence before the nations of the earth of being a republic and having "equality before the law" or else let us become the republic we pretend to be.

To further celebrate and commemorate the 19th Amendment this year, let us not take for granted our precious right to vote, and let us rededicate ourselves to removing the barriers that remain in women's paths.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim August 26, 1994, as Women's Equality Day. I call upon the citizens of our great Nation to observe this day with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this eighteenth day of August, in the year of our Lord nineteen hundred and ninety-four, and of the Independence of the United States of America the two hundred and nineteenth.

William J. Clinton

[FR Doc. 94–20872
Filed 8–19–94; 5:12 pm]
Billing code 3195–01–P

Presidential Documents

Executive Order 12924 of August 19, 1994

Continuation of Export Control Regulations

By the authority vested in me as President by the Constitution and the laws of the United States of America, including but not limited to section 203 of the International Emergency Economic Powers Act ("Act") (50 U.S.C. 1702), I, WILLIAM J. CLINTON, President of the United States of America, find that the unrestricted access of foreign parties to U.S. goods, technology, and technical data and the existence of certain boycott practices of foreign nations, in light of the expiration of the Export Administration Act of 1979, as amended (50 U.S.C. App. 2401 *et seq.*), constitute an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States and hereby declare a national emergency with respect to that threat.

Accordingly, in order (a) to exercise the necessary vigilance over exports and activities affecting the national security of the United States; (b) to further significantly the foreign policy of the United States, including its policy with respect to cooperation by U.S. persons with certain foreign boycott activities, and to fulfill its international responsibilities; and (c) to protect the domestic economy from the excessive drain of scarce materials and reduce the serious economic impact of foreign demand, it is hereby ordered as follows:

Section 1. To the extent permitted by law, the provisions of the Export Administration Act of 1979, as amended, and the provisions for administration of the Export Administration Act of 1979, as amended, shall be carried out under this order so as to continue in full force and effect and amend, as necessary, the export control system heretofore maintained by the Export Administration regulations issued under the Export Administration Act of 1979, as amended. The delegations of authority set forth in Executive Order No. 12002 of July 7, 1977, as amended by Executive Order No. 12755 of March 12, 1991; Executive Order No. 12214 of May 2, 1980; Executive Order No. 12735 of November 16, 1990; and Executive Order No. 12851 of June 11, 1993, shall be incorporated in this order and shall apply to the exercise of authorities under this order.

Sec. 2. All rules and regulations issued or continued in effect by the Secretary of Commerce under the authority of the Export Administration Act of 1979, as amended, including those published in Title 15, Subtitle B, Chapter VII, Subchapter C, of the Code of Federal Regulations, Parts 768 through 799, and all orders, regulations, licenses, and other forms of administrative action issued, taken, or continued in effect pursuant thereto, shall, until amended or revoked by the Secretary of Commerce, remain in full force and effect as if issued or taken pursuant to this order, except that the provisions of sections 203(b)(2) and 206 of the Act (50 U.S.C. 1702(b)(2) and 1705) shall control over any inconsistent provisions in the regulations. Nothing in this section shall affect the continued applicability of administrative sanctions provided for by the regulations described above.

Sec. 3. Provisions for administration of section 38(e) of the Arms Export Control Act (22 U.S.C. 2778(e)) may be made and shall continue in full force and effect until amended or revoked under the authority of section 203 of the Act (50 U.S.C. 1702). To the extent permitted by law, this order also shall constitute authority for the issuance and continuation in full force and effect of all rules and regulations by the President or his

delegate, and all orders, licenses, and other forms of administrative actions issued, taken, or continued in effect pursuant thereto, relating to the administration of section 38(e).

Sec. 4. Executive Order No. 12923 of June 30, 1994, is revoked, and that declaration of emergency is rescinded. The revocation of Executive Order No. 12923 shall not affect any violation of any rules, regulations, orders, licenses, and other forms of administrative action under that order that occurred during the period the order was in effect.

Sec. 5. This order shall be effective as of midnight between August 20, 1994, and August 21, 1994, and shall remain in effect until terminated.

William J. Clinton

THE WHITE HOUSE,
August 19, 1994.

[FR Doc. 94-20873
Filed 8-19-94; 5:09 pm]
Billing code 3195-01-P

federal register

Tuesday
August 23, 1994

Part VIII

Department of Transportation

Maritime Administration

Merger of Approved Trustee; Bank of New York; Notice

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Merger of Approved Trustee; Bank of New York

Notice is hereby given that Irving Trust Company, New York, New York, merged with and into The Bank of New York, 101 Barclay Street, New York, New York 10286, under the name of The Bank of New York as the surviving corporation in the merger.

Dated: August 15, 1994.

By Order of the Maritime Administrator

James E. Saari,

Acting Secretary.

[FR Doc. 94–20571 Filed 8–22–94; 8:45 am]

BILLING CODE 4910–81–M

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H.R. 4790/P.L. 103–300

To designate the United States courthouse under construction in St. Louis, Missouri, as the "Thomas F. Eagleton United States Courthouse". (Aug. 19, 1994; 108 Stat. 1557; 1 page)

S.J. Res. 178/P.L. 103–301

To proclaim the week of October 16 through October 22, 1994, as "National Character Counts Week". (Aug. 19, 1994; 108 Stat. 1558; 2 pages)

Last List August 22, 1994

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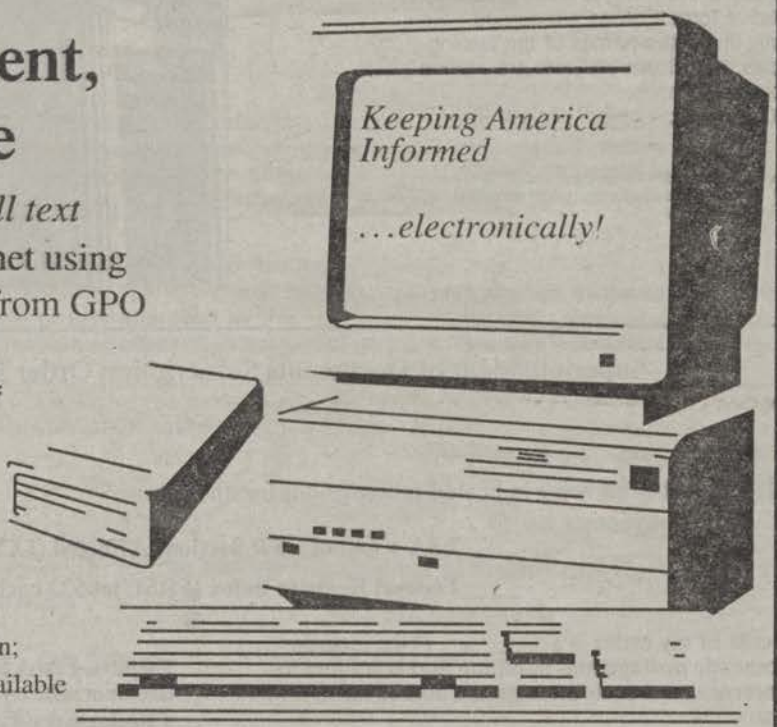

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